



January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9123-P: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

Thank you for the opportunity to provide comment on the *Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications* proposed rule.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

AHIMA commends CMS for offering a number of proposals in this proposed rule that seek to further integrate clinical and administrative data, which can improve the patient experience, enhance efficiency, and reduce burden for providers. Processes that require the exchange of clinical data to support administrative processes generally involve a considerable amount of work, including phone calls, use of payer portals, and faxes. Prior authorizations (PA) for tests, procedures, and medications, inpatient authorizations, and medical necessity reviews, all impose significant burdens on providers and patients and raise administrative costs. In some cases, they can also delay treatment and negatively impact patient outcomes.¹

¹Available at: <https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf>.

AHIMA offers comments on the following high-level issues, in addition to more detailed comments regarding certain aspects of the proposed rule.

Alignment/Standardization of Prior Authorization Requirements

AHIMA supports CMS' efforts under the proposed rule to reduce provider burden. However, we are concerned that the rule does not adequately address the standardization of PA requirements themselves, including documentation requirements. Indeed, a key challenge identified by the CMS DRLS Work Group was the variability of rules and documentation requirements across payers. This in turn, led to a recommendation by the Work Group that CMS consider analyzing federal payers' rules for opportunities to align. It is important to note that the ONC ICAD Taskforce recommended that CMS work with ONC and other federal actors to establish consistent processes and guidelines for PA rule sets to apply to CMS, MA, and other federally controlled or contracted plans. This recommendation included simplifying rules, and removing rules that have high burdens (e.g., those that are frequently approved, frequently overturned on appeal, or otherwise have low utility). We seek clarity from CMS as to how the proposed rule will further align and standardize PA requirements beyond automating PA transactions.

Semantic Interoperability

AHIMA is concerned that the proposed rule does not include a process to advance standards convergence. Better integration of administrative and clinical health data, including tools for automation, could bring significant benefits for improved patient experience and decreased provider burden. However, significant barriers beyond the technical approaches need to be overcome. One of these barriers is the need for alignment and accuracy of vocabulary standards to ensure the fidelity of the data throughout its lifecycle.

Today, clinical and administrative data often rely on different standards for similar concepts (such as SNOMED versus ICD for problems and diagnoses) and we lack a consensus-based map to accurately and consistently translate across them. Successful integration of these two distinct data streams will only be successful if it builds from a detailed understanding of how code sets are used for administrative and clinical purposes and addresses mapping issues. Otherwise, the data may lack semantic interoperability and not hold the same meaning for those who generate it and those who use it. It is unclear how the proposed rule intends to harmonize standards to create a consistent set of code sets, content, and services. Harmonizing standards that use an underlying data model could help to address multiple clinical and administrative workflows, thereby reducing provider burden and allowing data to flow automatically.

The ICAD Task Force address this issue extensively in its report, and recommended that ONC work with CMS, the National Library of Medicine, and relevant value set authorities to "harmonize code and value sets to serve clinical and administrative needs." Without this work, automation of the PA process could unintentionally create misunderstanding and result in the need for manual work-arounds to address inconsistencies.

As translators of clinical data for standard administrative data transactions, health information professionals can play a role in helping to understand the implications of differences between the varying vocabulary standards and in addressing coding accuracy and clinical documentation integrity. We welcome the opportunity to work with the CMS on this topic and to share our members' expertise in this critical area.

Proposed Rule Limited to Prior Authorization

AHIMA supports CMS' intent in the proposed rule to improve the patient experience and access to care, while reducing burdens for patients, providers, and payers. However, we note that there are other use cases that involve providers sharing clinical data with payers including concurrent review (e.g.--utilization review and case management) as well as post-discharge processes (e.g.--medical necessity reviews.) We hope that as CMS continues to address reducing provider burden and improving the patient experience, the agency will consider identifying additional opportunities that could benefit from increased automation and the convergence of clinical and administrative data streams.

Adoption of Standards for Health Care Attachment Transactions

AHIMA supports the naming of a HIPAA attachment standard as we believe it would be a positive step forward to establishing a national approach to exchanging clinical data to support clinical and administrative processes. We recognize that the attachment standard is a separate rulemaking, however, we ask for clarification on how this proposed rule intends to interact with the forthcoming attachment standard proposed rule.

Inclusion of Medicare Advantage Plans and Medicare Fee-for-Service (FFS)

CMS proposes to expand certain policies finalized in the CMS Interoperability and Patient Access final rule for state Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the federally facilitated exchanges (FFE).

AHIMA is disappointed that the expansion of these proposed policies does not cover Medicare Advantage organizations or Medicare FFS. Including Medicare Advantage organizations and Medicare FFS under this proposal is critically important to aligning administrative efficiency objectives across CMS as recommended by the ONC ICAD Task Force. Inclusion of these payers is also important to ensure that all stakeholders are "moving together" to create more certainty and consistency for providers and payers when adopting new standards and specifications. We encourage CMS to move expeditiously in expanding adopted policies to Medicare Advantage plans and Medicare FFS.

Provider Perspective on Operational Considerations and Business Rules

AHIMA seeks clarity on the intended impact of this rule on providers' workflow and operations. New standards and approaches must reflect operational considerations such as how information flows through the health care system and the technical systems that are needed. This includes consideration of the business rules. For example, what assurances are in place to ensure that the information retrieved does not go beyond what should be allowable? Which party assumes responsibility if the information of an incorrect patient is shared due to misidentification? Addressing these operational considerations is necessary to achieve the promise of converging clinical and administrative data. We believe this requires the participation of all stakeholders, including providers. We encourage CMS to work with ONC to support the engagement of providers in the further development of these standards and we welcome the opportunity to bring our own expertise and experience in translating across clinical and administrative domains.

II. Provisions of the Proposed Rule

A. Patient Access API

Beginning January 1, 2023, CMS proposes to require state Medicaid FFS programs, Medicaid managed care plans, state CHIP FFS program, CHIP managed care entities, and QHP issuers on the FFEs to require payers to make available to patients information about any pending and active prior authorization decisions (and related clinical documentation forms) for items and services via the Patient Access API no later than one (1) business day after a provider initiates a prior authorization request or there is a change in status for the prior authorization.

AHIMA supports CMS' proposal to require payers under these programs to make available to patients any pending and active prior authorization decisions (and related clinical documentation forms) for items and services within one business day after a provider initiates the PA request. Patients and caregivers need to be at the center of administrative workflows and having access to such information provides greater transparency into the process—including an opportunity for patients to better understand the items and services that require PA and how such determinations are made. Additionally, having access to such critical information may offer patients and their caregivers insight into the status of a PA request and provide an opportunity to inquire when there is a delay in care.

We are concerned that the proposed rule only speaks to prior authorization for items and services, and that it leaves out medications. Given the growing number of expensive medications used in medical care, it is important that individuals, their caregivers, and their medical teams have access to the same information regarding prior authorization for medications as for items and services. Leaving out this set of treatments also will create significant operational challenges, to the extent that prior authorization for medications continues to rely on manual processes while automated processes are adopted for items and services.

Privacy Policy Attestation

Beginning January 1, 2023, for state Medicaid FFS programs, Medicaid managed care plans, state CHIP FFS program, CHIP managed care entities, and QHP issuers on the FFEs, payers under these programs must establish, implement and maintain a process for requesting an attestation from a third-party application developer requesting to retrieve data via the Patient Access API that indicated the application adheres to certain privacy provisions.

AHIMA supports CMS' proposal to require payers under these programs to implement and maintain a process for requesting a privacy policy attestation from a third-party application developer that is requesting to retrieve a patient's health information via the Patient Access API. While HIPAA governs health privacy in traditional healthcare settings, an increasing number of consumer-facing technologies, applications, products, and services that access, produce and manage health information are not bound by or required to abide by the rules established under HIPAA. As a result, the type or level of protections under HIPAA, including a notice of privacy practices and restrictions on the sale, use, and reuse of PHI by third parties, are not afforded to individuals. Requiring impacted payers to implement such a process for requesting an attestation will not only provide individuals with a better understanding of how their health information may be used by a third party application developer, but also offer an informed choice to the individuals as to whether they want their health information to be shared with a third party application depending upon the application developer's attestation.

AHIMA also agrees with CMS' approach to not be overly prescriptive in how payers could implement this process. Industry third parties could play an important role in assessing and helping application developers attest that they have established a minimum set of privacy provisions to be compliant with this requirement.

B. Provider Access APIs

CMS proposes to require impacted payers to establish, implement, and maintain a process to facilitate generating each provider's current enrollee roster to enable the proposed payer-to-provider data sharing via the Provider Access API. To facilitate this data sharing, providers will need to give payers a list of patients whose data they are requesting.

AHIMA seeks clarity on how providers will need to provide payers with the list of patients whose data they are requesting. We understand that CMS' Data at the Point of Care (DPC) pilot will examine a process to allow providers to add active patients to a roster through self-attestation, which is checked against claims to verify that the provider has furnished services to the patient. We hope the results of this testing will be made publicly available and seek information on whether the DPC pilot intends to consider the testing of a process for new patients that may be added to a provider's roster.

CMS seeks comment on a number of policies concerning prior authorization over time and across payers. These include:

- Whether there should be certain restrictions regarding requirements for repeat PA for items and services for chronic conditions, or whether there can be approvals for long term authorizations;
- Whether a PA decision should follow a patient when they change from one qualified health plan on the Exchange to another, or to another health plan impacted by this proposed rule, and under what circumstances that PA could follow a patient from payer to payer; and
- Whether PAs should be valid and accepted for a specified amount of time, as well as who should determine how long an existing approved PA from a previous payer should last, and whether PA should be regulated by an amount of time and/or by conditions.

AHIMA believes that in each of these circumstances, a patient's welfare should guide both the term of the PA and whether an existing approved PA should follow to another health plan impacted by this proposed rule. Furthermore, there may be circumstances where a patient switches his or her plan because a previous payer denied a PA request despite the judgement of his or her medical providers. For that reason, we believe that patients should determine whether a PA follows him or her from payer to payer.

CMS also requests input on solutions to standardizing PA forms, including the possibility of developing an HL7 FHIR based questionnaire for PA requests.

As we note in our general comments, further standardization of a universal set of data elements that could be called upon to address multiple clinical and administrative needs could help to further standardize PA forms and minimize the use of questionnaires.

C. Reducing the Burden of Prior Authorization through APIs

CMS proposes to require beginning January 1, 2023, that Medicaid managed care plans, CHIP managed care entities, state Medicaid and CHIP FFS programs, and QHP issuers on the FFEs implement and

maintain a FHIR-based DRLS API that could be integrated with a provider's EHR to allow providers to electronically locate PA requirements for each specific payer from within the provider's workflow.

AHIMA appreciates CMS' intent under the proposed rule to improve transparency and communication between providers and payers by streamlining access to information about PA and related documentation requirements. However, we are concerned about the readiness of the FHIR-based DRLS API to apply to all covered items and services when the Medicare FFS DRLS Prototype only examined rule sets for ten select topics. In addition, it is also unclear what integration of the DRLS will look like at the provider level. We seek clarity on whether providers will continue to be required to transition from application to application, much like the current experience of having to manage multiple payer portals, in order to locate the PA requirements for each payer.

E. Adoption of Health IT Standards and Implementation Specifications

CMS proposes to require the use of specific standards at 45 CFR 170.215 proposed for adoption by the Office of the National Coordinator for Health IT (ONC) by impacted payers.

The health care field has made tremendous progress in standards-based collection, use and sharing of health information through the leadership of the federal government in standards adoption. That said, AHIMA is concerned about the maturity of the Implementation Guides proposed under this rule. In particular, the ONC Interoperability Standards Advisory (ISA) denotes several of these Implementation Guides to be "In Development" and requiring "feedback" to evaluate their implementation maturity and adoption levels. Indeed, HL7's DaVinci Implementation Guide Dashboard notes that of the eight Implementation Guides proposed for adoption in this rule, only two have actually been published while others appear to still be in development and/or near publication. We seek clarity from ONC and CMS on the readiness of the proposed standards and specifications, including information on the results from pilots of the implementation guides and current levels of adoption in production environments.

III. Requests for Information

D. Reducing Burden and Improving Electronic Information Exchange of Prior Authorizations

CMS is seeking information on whether the CMS CoP/CfC requirements for hospitals and other providers and suppliers would be an appropriate lever by which CMS should propose new or additional provisions that would require the electronic request and receipt of PA decisions and if so, under which provisions would this best be accomplished. CMS also seeks information on whether it should consider adding a measure to the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals and the MIPS Promoting Interoperability performance category for clinicians and groups to encourage the use of electronic PA through a payer's Prior Authorization Support (PAS) API.

In general, we recommend that CMS consider deploying only positive, targeted incentives to incent hospitals, clinicians, and suppliers to use electronic prior authorization solutions. Positive incentives would recognize the newness of these approaches and the necessary learning curve for providers to obtain the necessary technology, change workflows, and educate the workforce. This is particularly important for smaller facilities and practices that may lack the resources needed to implement new technologies, training, and processes to leverage electronic prior authorization solutions.

F. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Data

CMS seeks information on the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools.

In general, AHIMA supports the collection, access, sharing, and use of social determinants of health (SDoH) to enrich clinical decision-making and improve health outcomes, public health, and health inequities in ways that are culturally respectful. A key challenge that arises in representing and exchanging social risk and social needs information is the lack of data standards to encourage the collection, use and exchange of SDoH data. Enhanced interest in leveraging SDoH data has led to more measures of different social risk factors and indicators. However, lack of agreement on which data to collect and lack of data standardization has limited the collection and sharing of SDoH, often leading to confusion about the tools available to providers. AHIMA believes that a set of standard concepts and definitions for SDoH must be identified including identification of existing medical coding vocabulary gaps to document and capture standardized SDoH data elements. For that reason, we are active participants in The Gravity Project's work to address some of these issues. We also believe that consideration must be given to ensuring that the processes for updating vocabularies and code sets routinely includes consideration of SDoH data needs.

CMS seeks information on barriers to the exchange of social risk and social needs data across providers as well as key challenges related to the exchange of social risk and social needs data between providers and community-based organizations.

A key barrier to the exchange of social risk and social needs data between providers and community-based organizations is the lack of digital infrastructure and robust technical capabilities to support functional, structural and semantic interoperability across clinical and community-based organizations and service providers. Successful approaches today that integrate social needs with clinical care are often manual information exchanges, human-capital intensive, involve unstructured data, and may lack consistency or data standardization within or between health and social care settings.² For that reason, we support the prioritization of a set of standardized data elements to be included in electronic health records (EHRs). This includes the development and testing of consensus-based standards to enable the electronic exchange of SDoH data. Moreover, we believe that public policy should encourage data governance policies to support data sharing and data integrity, while promoting positive referral feedback loops to enhance care coordination.

Another challenge in exchanging social risk and social needs data between providers and community-based organizations is recognition of disparate privacy laws, rules and guidelines that govern the privacy and security of both clinical and non-clinical information. We believe it is necessary to consider these privacy and security issues that arise when collecting and sharing electronic health information outside of the scope of HIPAA as well as other privacy-related concerns such as consent management and the appropriate sharing of information (while ensuring that only the minimum necessary information is exchanged and limited to the specific transaction in question).

² Available at: <https://www.nationalacademies.org/our-work/integrating-social-needs-care-into-the-delivery-of-health-care-to-improve-the-nations-health>.

Thank you for the opportunity to comment on this proposed rule. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President, Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,

A handwritten signature in cursive script that reads "Wylecia Wiggs Harris".

Dr. Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA