American Hospital Association™

Advancing Health in America

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
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 Specification

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information notice of proposed rulemaking (NPRM).

The AHA commends the Centers for Medicare & Medicaid Services (CMS) for taking action to remove inappropriate barriers to patient care by streamlining the prior authorization processes for the impacted health plans. While prior authorization can be a helpful for tool for ensuring patients receive appropriate care, the practice is too often used in a manner that leads to dangerous delays in treatment, clinician burnout, and more waste in the health care system. The proposed rule is a welcome step toward helping clinicians focus their limited time on patient care rather than paperwork.

However, the AHA is deeply disappointed that CMS chose not to include Medicare Advantage (MA) plans, many of which have implemented abusive prior authorization processes that act as a detriment to the provision of efficient and

timely patient care. In addition, while hospitals and health systems appreciate CMS establishing timeframes for prior authorization decisions, we believe the proposed timelines for urgent and non-urgent care are insufficient to protect patients and promote appropriate care. **We urge CMS to reconsider the omission of MA plans and tighten the prior authorization decision timeframes in order to promote timely care and patient safety**.

Our detailed comments follow:

BACKGROUND

According to the America's Health Insurance Plans, prior authorization is implemented by health plans "to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient."[1] Philosophically, we agree with these laudable goals, and, indeed, some health plans use prior authorization in ways that accomplish them. However, many health plans apply prior authorization requirements in ways that create dangerous delays in care, contribute to clinician burnout, and drive up costs for the health care system.

In addition, inefficient prior authorization can negatively impact quality of care. According to a 2019 American Medical Association survey of more than 1,000 physicians, 90% of respondents indicated that prior authorization "had a significant or somewhat negative clinical impact, with 24% reporting that prior authorization had led to a serious adverse event such as a death, hospitalization, disability or permanent bodily damage, or other life-threatening event for a patient in their care."[2] The federal government also has acknowledged the risk of delays in care caused by prior authorization requirements, which is why it urged health plans to ease such requirements during the COVID-19 public health emergency, stating "New guidance for individual and small group health plans encourages issuers to utilize flexibilities related to utilization management processes, as permitted by state law, to ensure that staff at hospitals, clinics, and pharmacies can focus on care delivery and ensure that patients do not experience care delays."[3]

Prior authorization puts a heavy burden on clinicians and contributes to workforce burnout. According to the National Academies of Medicine, "Among clinicians, burnout is associated with job demands related to workload, time pressure, and work

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[1] America's Health Insurance Plans, "Prior Authorization Frequently Asked Questions." Accessed at: https://www.ahip.org/wp-content/uploads/Prior-Authorization-FAQs.pdf
[2] American Medical Association, "2019 AMA Prior Authorization (PA) Physician Survey." Accessed at: https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf
[3] Accessed at: https://www.cms.gov/newsroom/press-releases/cms-news-alert-april-23-2020

inefficiencies, such as burdensome administrative processes which divert clinicians' attention away from patients and detract from patient care."[4]

One of the most frustrating aspects for providers and patients is the variation in prior authorization submission processes. Plans vary widely on accepted methods of prior authorization requests and supporting documentation submission. While some plans accept electronic means, the most common method remains using fax machines and contacting call centers, with regular hold times of 20 to 30 minutes. In addition, plans offering electronic methods of submission most commonly use proprietary plan portals, which require a significant amount of time spent logging into a system, extracting data from the provider's clinical system and completing idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. For each plan, providers and their staff must ensure they are following the right rules and processes, which may change from one request to the next. Inevitably, providers commit inadvertent errors that result in denials that must be reprocessed or appealed.

EXCLUSION OF MEDICARE ADVANTAGE PLANS

In the proposal, CMS places new requirements on Medicaid and Children's Health Insurance Program (CHIP) managed care plans, state Medicaid and CHIP fee-for-service programs, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs), while also indicating that Medicare fee-for-service will be adhering to the requirements. The notable exclusion of MA plans is extremely troubling and significantly reduces the potential impact of the regulation.

The regulation establishes that impacted plan beneficiaries, including those belonging to managed care plans, will experience improved efficiencies in the manner in which they receive care by reduced timelines and procedural improvements. Currently, approximately one-third of all Medicare beneficiaries (approximately 22 million people) are enrolled in a private MA health plan, with the Congressional Budget Office projecting this percentage to increase to approximately 47% by 2029.[5] **In order to promote procedural improvements and prevent negative health outcomes associated with delays in care for these beneficiaries, we urge CMS to require MA plans to adhere to the requirements set forth in this proposal.**

MA plans have an established history of inappropriately utilizing prior authorization to deny necessary treatment for patients. According to a 2018 report by the Department of Health and Human Services Office of Inspector General, MA organizations overturned

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[4] National Academies of Medicine, "Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being," Oct. 2019. Accessed at: https://nam.edu/wp-content/uploads/2019/10/CR-report-highlights-brief-final.pdf
[5] https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2019/#:~:text=In%202019%2C%20one%2Dthird%20(,rate%20as%20the%20prior%20year.

75% of prior authorization denials that were appealed between 2014 and 2016.[6] This elucidation of such widespread inappropriate denial of necessary care establishes that MA plan prior authorization practices are in dire need of reformation, making their exclusion from this rule particularly consequential.

Furthermore, the absence of MA plans limits the potential return on investment for providers wishing to take advantage of the rule's procedural improvements. Providers benefit from standardization of billing policies across payers, as implementing alternate protocols depending on a patient's insurer carrier requires dual procedures for completing the same process, which creates inefficiencies. While some duplicity may be inevitable as standards are developed and change is introduced, a health care provider must balance the inherent inefficiencies of having multiple ways of performing the same task against the intended benefits of the enhanced method. In order to encourage providers to invest the resources in the technology necessary to complete the processes described in the rule, CMS should make the rule applicable to a wide-spectrum of patients. By excluding payers covering such a substantial segment of the beneficiary population, a provider's incentive to adopt this new methodology is significantly reduced.

To the extent that leaving MA plans out of the proposed rule was due to concerns about the plans' ability to implement this sophisticated technology, it should be noted that each of the four largest MA organizations, making up over two-thirds of the market, (United Healthcare, Humana, Blue Cross/Blue Shield Association, and CVS/Aetna) are members of the HL7 Da Vinci Initiative, the organization responsible for crafting the Fast Healthcare Interoperability Resources (FHIR) transactions being implemented through this rule. As a result, these organizations have already invested significant resources into these technologies and should be among the most ready participants to implement these solutions.

TIMELINESS STANDARDS

CMS proposes to require Medicaid and CHIP plans to deliver prior authorization decisions of health services in no later than seven calendar days after the date of the receipt of the request for a standard determination and 72 hours following the receipt of the request for an expedited determination. **While pleased to see restrictions being placed on prior authorization timelines, which frequently delays the delivery of medically necessary care, we find these particular timeframes to be unreasonably lenient and insufficient to adequately address the problem.**

Unlike other transactions between a provider and health plan, prior authorization involves clinical information and has a direct impact on prospective patient care. A prior

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[6] U.S. Department of Health and Human Services Office of Inspector General. "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials," OEI-09-16-00410. September 2018.

authorization request is often the final barrier between a patient and the implementation of their provider's recommended treatment, making judicious processing of such transactions extremely important. Prior authorization has been shown to cause significant delays in care, frequently leading to negative clinical outcomes for patients.[7] Unfortunately, the health care field has struggled to implement an efficient and standard method of delivering the clinical documents necessary to process prior authorizations, often resorting to slow and non-digitized delivery, such as fax machines and the mailing of documents through the postal service. These inefficiencies can lead to devastating delays spent waiting for authorizations, such as suspected cancer patients anxiously waiting days or even weeks for a diagnostic scan or a psychiatric patient spending extra time in an emergency department while waiting for placement in an appropriate care facility.

The Prior Authorization Support FHIR application programming interface (API) proposed under this regulation could effectively eliminate administrative delays caused by slow delivery of medical documents, as the implementation guide boasts the ability to deliver clinical information in real-time. As a result of having the clinical information delivered in such an expeditious manner, health plans should have the capability to determine whether or not the provider has met their established medical necessity threshold in a much timelier manner. Patients should not be forced to wait to receive care for longer than is necessary. **We recommend that plans be required to deliver prior authorization responses within 72 hours for standard, non-urgent services and 24 hours for urgent services for transactions utilizing the FHIR technology established under this rule**.

In addition, the proposed rule allows plans to extend prior authorization deadlines by up to 14 days if the plan determines that the submitted medical documentation is insufficient to make a determination. We find this to be inappropriate, particularly in light of the Documentation Requirement Lookup Service (DRLS) API capabilities prescribed in the regulation. If a provider utilizes the FHIR transactions required in the regulation, their electronic health record (EHR) system should have known the information necessary for prior authorization decision-making to occur. Absent a provider failing to deliver some of the informational requests included in the DRLS processes, plans should not be permitted to extend a prior authorization determination. In addition, regardless of how prior authorization is requested, permitting additional time for additional information may incentivize a plan changing documentation requirements after the fact to excuse a delay in approving care.

Furthermore, we disagree with the proposal's timeliness standards not being applicable to qualified health plan (QHP) issuers on the FFE. Beneficiaries on these plans should be entitled to the same protections as the others covered under this regulation. These plans should not be allowed to enact prior authorization policies that exceed the

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[7] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

timeframes established in the NPRM. Such discrepancy further limits the scope of this regulation and reduces its ability to improve care delays for these patients.

INCORPORATION OF APPLICATION PROGRAMMING INTERFACE (API) TECHNOLOGY

The NPRM calls for the creation of FHIR-based APIs to facilitate the exchange of information necessary to streamline prior authorization processes directly from a provider's EHR system. **We support this proposal, as the AHA has long advocated for the creation of electronic prior authorization standards that integrate with provider clinical information systems in order to eliminate time spent transposing clinical data from one system to another.**

We note that the specific implementation guides are still part of a continuous build and remain subject to changes. In addition, we are unaware of any wide-scale demonstrations showing how this technology would function in a real-world health care environment. In order to clearly establish the benefits that this technology would provide stakeholders, we encourage CMS to conduct such demonstrations prior to the Jan. 1, 2023 implementation date.

Documentation Requirement Lookup Service and Prior Authorization Support APIs

CMS proposes to require impacted health plans to implement a DRLS platform that would enable providers to submit prospective procedures and determine whether they are subject to prior authorization and, if so, ascertain the necessary documentation for the adjudication of the request.

We applaud CMS for recognizing the difficulty that providers often face when trying to determine the potential prior authorization requirements for a particular service. As a result of the significant variability between health plans' prior authorization services lists and approval criteria, providers often are uncertain as to whether a particular recommended patient service requires prior authorization and which documents the plan requires for approval. We believe that EHR-based technology that allows providers to determine prior authorization requirements at the point of care will significantly improve the delivery of care, reducing much of the ambiguity associated with prior authorization.

The proposal requires the DRLS platform to be built according to the DaVinci Clinical Decision Support and Documentation Templates and Rules (DTR) implementation guides. While incorporating the necessary connections for easily transmitting information, we have some concerns about the specific access to provider systems granted under the guides. **We encourage CMS to ensure that such access is limited only to the specific information needed for adjudication of a prior authorization request rather than unfettered access.**

Prior Authorization Support Technology

In addition to the DRLS platform, CMS proposes a requirement that plans implement a FHIR-based Prior Authorization Support (PAS) API that gives providers the capability to send prior authorization requests and receive responses electronically within their existing workflow. **We support the use of EHR technology for the submission and processing of prior authorizations, as it empowers clinicians to utilize this information during treatment planning and creates the potential for meaningful, real-time access to this data.** The proposal utilizes the Health Insurance Portability and Accountability Act (HIPAA)-named X12 278 transaction as an intermediary between the provider's and the payer's FHIR-based systems. We agree with the incorporation of this standard, as it ensures that providers are entitled to the protections afforded by the HIPAA regulations and enables the consistent delivery of information. However, the translation of FHIR information into and out of the 278 will likely require the use of clearinghouses serving as middlemen in the process, which reduces the provider and industry savings achieved in the process. **As a result, we encourage CMS to create a pathway toward a streamlined, consistent process for plans and providers to exchange these transactions directly without the need for clearinghouse translation.**

PRIOR AUTHORIZATION DATA REPORTING REQUIREMENTS

The AHA was pleased to see that CMS included reporting requirements for plans surrounding their prior authorization processes. Specifically, we believe that by requiring plans to report the percent of prior authorization requests approved, denied, and denials overturned on appeal, and the average time between submission and determination, the rule promotes transparencies and provides the capabilities of creating accountability, each of which are severely lacking in this space. While there is a significant amount of research and reporting that establishes the burden that inefficient prior authorizations have on patients and providers, there are limited resources available for determining particularly problematic plans. In creating a public reporting mechanism for these essential data, the proposed regulation provides this essential transparency.

In order to ensure that the reporting of this data fosters prior authorization improvements as intended, we encourage CMS to create enforcement mechanisms that hold plans accountable for unacceptable reported metrics. This will enable meaningful change to take place where it is needed most.

PATIENT ACCESS API

CMS proposes to require affected plans to include, as part of the Patient Access API established in the Interoperability and Patient Access final rule, information about the patient's pending and active prior authorization decisions to ensure they have a better understanding of the prior authorization process and its impact on their care. We agree

that a program that increases the transparency surrounding the prior authorization process would be beneficial for patients, as these utilization management policies frequently have a significant impact on their care.

The proposal also envisions patients utilizing the Patient API to potentially help providers deliver information to payers to facilitate a successful prior authorization request. **Although we welcome patient input on these processes as they see fit, such involvement should not be expected or required.** Many of the procedures subject to prior authorization are complex and major medical processes (e.g. cancer treatments, advanced imaging, surgeries). At such a time, patients are likely to have significant health concerns and may not wish to be burdened with administrative tasks, especially those as complex as prior authorization and medical necessity determinations often can be. We recommend that the regulation be clarified to ensure that patient involvement is completely voluntary.

PROVIDER ACCESS API

The proposal also establishes the Provider Access API, a FHIR-based platform that allows a provider to access patients' claims and encounter data, clinical data maintained by the plan, formulary or preferred drug list data, and information on pending and active prior authorization decisions. We strongly support these provisions, which help ensure that all relevant information is available to providers when determining a patient's course of treatment.

PAYER-TO-PAYER API

In the Interoperability and Patient Access final rule, CMS finalized a requirement that impacted plans exchange patient health information with a patient's subsequent health plan, enabling the maintenance of a comprehensive health record with their active plan. In the current proposal, CMS seeks to add information about pending and active prior authorizations to this data set.

Due to the impact that prior authorizations often have on patient care, we commend CMS for requiring this information to be exchanged with subsequent plans at a patient's request. Particularly for patients battling chronic conditions and those whose coverage changes during the course of a treatment, prior authorizations can disrupt medical care for which medical necessity has been established already. In order to ensure that these patients do not experience delays or negative outcomes resulting from prior authorization, we recommend that CMS require subsequent plans to honor prior authorizations for ongoing care that were approved by a patient's previous plan.

COMPLETE DENIALS

The proposal acknowledges the importance of sufficient information in prior authorization denials, as providers must understand why a request is denied so that they can either re-submit it with updated information, identify alternatives, appeal the decision or communicate the decision to their patients. Under the terms of the proposal, payers would be required to provide a specific reason a prior authorization request is denied, such as indicating necessary documentation was not provided, the services are not determined to be medically necessary, or the patient has exceeded limits on allowable care for a given type of item or service, so that a provider can determine what their best next steps may be to support getting the patient the care needed in a timely manner.

This proposal would help address a significant problem in the field, as providers and patients are often left without adequate explanation as to a denied prior authorization request. **We support this proposal and encourage CMS to establish enforcement mechanisms to ensure that plans are compliant with its requirements.** In addition, we encourage CMS to define "complete denials" to ensure that providers receive all of the relevant information in their appeal, such as appropriate clinical justification and information about appeals rights and deadlines.

REQUEST FOR INFORMATION ON REDUCING BURDEN AND IMPROVING ELECTRONIC INFORMATION EXCHANGE OF DOCUMENTATION AND PRIOR AUTHORIZATION

CMS requested information on current barriers to the electronic transmission of prior authorization requests and receipts. Specifically, CMS asks what additional levers it can utilize to push hospitals and other providers to utilize the technology proposed in the rule, including potentially including usage in the Medicare and Medicaid Conditions of Participation (CoPs) and including it in future Merit-Based Incentive Payment System (MIPS).

Inefficient prior authorization processes have routinely caused administrative burden for providers and inappropriate care delays for patients, and providers are eager to adopt more streamlined approaches. As a result, we have consistently advocated for the establishment an efficient, *standardized* electronic method of processing prior authorizations across the various payers with whom they interact. In keeping with this long-held position, we believe that **the best method of getting providers to adopt the technology is to increase the number of health plans that are required to utilize the proposed electronic methodology, establish meaningful prior authorization decision timelines, and release proven data establishing the administrative and fiscal savings made possible by its incorporation.**

The current X12 278 standard has proven insufficient in promoting increased efficiencies in this space. Much of this can be attributed to the lack of an attachment

standard for clinical documentation, and the ability of health plans to "pend" prior authorizations without the requisite clinical documentation. We note, however, that the current regulatory agenda includes an attachment standard that is scheduled to be released in February 2021. Depending on the specifics of this particular regulation, the currently named HIPAA standard could be greatly beneficial to the healthcare field when used in conjunction with a standardized method of submitting clinical documentation.

Among our most pressing concerns with the proposed regulation is that its limited scope and lengthy timeline requirements may reduce the likelihood that providers will make the technological investments to utilize its capabilities. Making significant changes to clinical and administrative workflows would take a significant amount of time and resources. Particularly amidst the extreme financial strain that the ongoing pandemic has placed on many hospitals, the investment of such resources may be limited only where there are recognizable, tangible and substantial benefits. The current proposed regulation, while representing a significant step forward, may fall short of offering such return on investment. CMS could greatly increase the attractiveness of this method by utilizing its authority to include MA plans and to require faster turnaround times for prior authorizations.

Additionally, we oppose mandating use of this technology in the CoPs, which are standards specifically targeted to ensure the safety and quality of care and carry extreme penalties for non-compliance. While IT functionality can support quality and safety, the extension of these requirements into this space seems misaligned with the intent of CoPs and unnecessary given existing regulations governing information exchange between providers and payers.

The exchange of information with others involved in the care of the patient is important, and there are CoPs currently in place that dictate the exchange of critical patient event information, such as:

- Recognize the patient's right to have a representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital [§482.13(b)(4)];
- Have in place a discharge planning process that assesses the needs of the patient, screens for the risk of adverse events post-discharge, creates a discharge plan of care, and initiates implementation of that plan, which includes communicating with the next care giver and the patient and/or family member [§482.13(b)(4)];
- Transfer any necessary information to the appropriate site for follow-up care, including: (i) the reason for transfer or discharge; (ii) the effective date of transfer or discharge; (iii) the location to which the resident is transferred or discharged; (iv) a statement of the resident's appeal rights; and information on how to obtain an appeal form and assistance in completing and submitting the appeal request; and several other pieces of information [§482.43(d)].

While the above requirements focus on what information must be provided to ensure safe and effective care for patients, they are agnostic as to the mechanism by which the information must be exchanged. To promote the efficient exchange of information between health plans and providers, Congress gave HHS the authority to establish and enforce standard administrative transactions in HIPAA.

The HIPAA administrative simplification provisions are the specific regulations controlling revenue cycle communications between health plans and providers, including prior authorization activities. These rules require health plans to offer standard electronic transactions, but only require providers to utilize this technology if they choose to interact electronically. This enables a provider time to allocate resources as appropriate and promotes optimal efficiency in health plan implementations. We see no reason to deviate from or duplicate this process with the proposed solution.

In general, the AHA has been supportive of establishing appropriate incentives to promote the adoption and use of technology that improves the safety, quality and efficiency of care for patients. However, the ongoing public health emergency has forced hospitals to redirect IT resources – budgets and staff – to critical COVID-19 priorities making the implementation of new technology extremely challenging in the current environment. As CMS contemplates additional, existing regulatory levers, such as the MIPS program, to advance this regulation we urge consideration of a runway to allow providers to gain experience with both the technology and associated changes in workflow. We welcome the utilization of incentives to promote greater provider adoption of this technology, including potentially establishing a MIPS Improvement Activity. Particularly in light of the constraints that the COVID-19 pandemic has placed upon hospitals and other providers, incentive programs can alleviate budgetary constraints and help providers make the initial investment to enact the efficiencies contained within this regulation.

REQUEST FOR INFORMATION ON REDUCING THE USE OF FAX MACHINES FOR HEALTH CARE DATA EXCHANGE

CMS notes that it is looking for ways to facilitate efficient, effective and secure electronic data exchange to help ensure more timely, better quality, and highly coordinated care. Although providers and payers have historically relied on fax technology as a primary method for sharing information, the data in those documents are not easily integrated electronically into a patient's medical record or shared in an interoperable way with other payers and providers.

We share CMS' belief that the use of fax machines is laborious and welcome solutions that enable more efficient exchange of clinical information. As CMS notes, fax machines were historically a widely accepted method of sending clinical data to payers and providers across the health care field. Although the technology was inefficient, it was

often still the easiest method of sending information, as all parties accepted faxed documents. As we detail throughout our comments, in order for providers to utilize an alternative to fax machines, CMS should push all payers to adopt a standard method of exchanging this data that is accepted by all of the various payers with whom a hospital interacts. Without a sufficient scope of payers and meaningful improvements in prior authorization processing timeframes, providers may continue to utilize less advanced yet widely accepted exchange methods.

REQUEST FOR INFORMATION ON SOCIAL RISK DATA

The AHA appreciates CMS' interest in the challenges hospitals face in collecting and using social risk data to better serve patients and communities, as well the agency's exploration of whether an acceleration of social risk data standards may be helpful. America's hospitals and health systems are deeply committed to identifying and eliminating disparities in health outcomes. Social risk factors can either facilitate or impede a person's ability to maintain or return to a state of health. This makes the availability and use of reliable, relevant social risk data important to improving health equity.

At the same time, we caution CMS against mandating the use standards for collecting and transmitting these data prematurely. As described below, hospitals and health systems have implemented a range of mechanisms to capture social risk data that align with the needs of the patients and communities they serve, all of which are resource intensive. While greater data standardization clearly could have important benefits, a precipitous mandate to use certain standards also could be disruptive to the field. Ultimately, the goal of social risk data standards should not be simply to capture and document data; rather, it should be to reduce health disparities and improve care for all. For that reason, we would urge CMS to adopt only those standards that receive extensive input from the field, are directly relevant to improving disparities and are flexible enough to meet the varied capabilities and needs of hospitals and communities.

Challenges with Capturing and Using Social Risk Data
Collecting social risk data, incorporating it into the clinical record and using it to shape the care plan is a complex and dynamic process. The AHA's 2019 report on screening for social needs describes in depth the processes and challenges that hospitals face with implementing social need screening tools.[8] As the report shows, hospitals and health systems face an array of choices in determining at what point of care to capture the information. They could use admission interviews conducted by an intake nurse. They could capture the information during outpatient visits using clinicians or other non-clinical members of the care team. They could have patients fill out paper forms or use electronic mechanisms. In some cases, more sensitive information (e.g.,

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[8] https://www.aha.org/system/files/media/file/2019/09/screening-for-social-needs-tool-value-initiative-rev-9-26-2019.pdf

issues around violence or abuse) may be best captured through conversations with a clinician the patient trusts rather than through forms. Hospitals generally make their choice of data collection approach based on the needs of their patient population and their own processes.

The initial capture of social risk factor data is only the beginning of the challenge for hospitals. It also is important to document the data in clinical and administrative records in ways that helps hospitals not only track broader trends across their patient populations, but also provide information relevant to clinicians at the point of care. **The AHA believes the ICD-10 CM codes related to social determinants of health (i.e., "Z codes") are an important tool for hospitals to capture the social needs of their patient populations.** The codes help hospitals document non-medical social risk factors that may influence a patient's health status, including education and literacy, employment, housing, lack of adequate food or water or occupational exposure to risk factors like dust, radiation or toxic agents. The codes can enable a number of hospital efforts to identify and address disparities, such as population-level trends analysis, and social determinant flags in EHR systems. That is why the AHA's Coding Clinic has encouraged hospitals to increase the utilization of these codes.[9] At the same time, given the resources required to collect social risk data, we would not recommend that the reporting of these codes be mandated at this time.

EHR Standards Challenges
Many hospitals also have pointed to EHRs as a potential mechanism for not only capturing social risk factor data in a more standardized fashion, but also making it accessible to clinicians at the point of care. This is especially true given that EHRs may be able to more rapidly catalog the inevitable changes to patients' specific social risk factors over time.

The EHR certification standards developed by the Office of the National Coordinator for Health IT (ONC) hold promise for promoting greater standardization of social risk factor data in EHRs. However, significant gaps in standards remain. ONC's EHR certification criteria, test procedures and test tools are used to confirm that an EHR can capture, incorporate and send data in accordance with standard codes. The certification criteria and the testing procedures for some data – such as demographics (as outlined in §170.315(a)(5)) – are specific.

However, for other data in the EHR certification standards – including many related to social risk factors – the testing approach is not prescribed. As a result, social risk data may be collected routinely but perhaps not consistently or in support of a patient population identified as needing particular services. For example, the social, psychological, and behavioral data certification criteria (§170.315(a)(15)) requires EHRs to be certified to capture data in eight domains: financial resource strain, education, stress, depression, physical activity, alcohol use, social connection and isolation, and

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[9] https://www.aha.org/system/files/2018-04/value-initiative-icd-10-code-social-determinants-of-health.pdf

exposure to violence. Certified EHRs are required to capture whether the individual provides a level of response to each domain but are not certified to indicate if the individual declined to respond to the question. The criteria also permit EHRs to capture information in text fields rather than structured codes. Furthermore, the testing approach for this certification criteria is self-declaration.

Additional work is needed to standardize the data collected in electronic form, test EHRs to confirm the consistent implementation of the standards, and crosswalk the standard data to social risk factor measures or well-established social risk factor screening tools. **The AHA recommends CMS collaborate with ONC, providers, and EHR and health IT vendors to develop or refine standards, implementation requirements and guidelines to support the effective capture and use of social risk data in EHRs.**

The successful development of these EHR standards could enable further development of tools to help identify and address social risk factors at the patient and population level. At the patient level, a positive screen for a social risk factor could provide a clinical decision support tool linking clinicians to internal or community partner resources that may benefit a particular patient. At the population level, hospitals may be able to use mapping and visualization tools to help illuminate geographic areas of communities that are particularly at risk, or better detect associations between social risk factors and health outcomes. This could better target interventions and hospital population health strategies.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Terrence Cunningham, director of policy, at tcunningham@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis & Development