November 20, 2019

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted electronically: AIProgramIntegrityRFI@cms.hhs.gov

Re: Request for Information (RFI) on Using Advanced Technology in Program Integrity

Administrator Verma:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on this Request for Information (RFI) on the use of advanced technology to ensure program integrity.

Informatics is the science of how to use data, information, and knowledge to improve human health and the delivery of health care services. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. AMIA members advance health and wellness by implementing and evaluating informatics interventions, innovations, and public policy across settings and patient populations, adding to our collective understanding of health in the 21st century through peer-reviewed journals and scientific meetings.

It is laudable that CMS seeks to leverage the science of informatics to improve program integrity, as AMIA believes that such "regulatory science" is simply informatics by another name. We are thus supportive of CMS exploring the use of emerging technologies to safeguard the resources that help fund health care for more than 60 million beneficiaries. We believe that our members' experiences with Artificial Intelligence/Machine Learning (AI/ML) and related technologies like clinical decision support (CDS) can inform CMS's approach to using Medicare dollars more efficiently and decreasing provider burden.

We note however that AI technology is still not nearly sufficiently developed to be able to support documentation review efforts at the individual note/service level, nor do we believe that it is likely to be viable for such applications within the next five years, or longer. Prior to any implementation, such tools would need to be rigorously tested against manually checked records to identify accuracy of the AI. Given the implications for providers – including financial, legal, and professional reputation – there would need to be a very low rate of false positive results of such approaches. If CMS were to continue with efforts to reduce the complexity of needed documentation, then it may be more feasible to design automated approaches for documentation checks.

As CMS considers the use of AI/ML medical record review technology for the future, we urge it to be mindful that the technology not drive an excessive focus on documentation, especially to the point where it can affect patient care. As we have commented to CMS previously[1], reimbursement incentives and fears of audit will continue to perpetuate the practice of overdocumentation absent structural change to reimbursement models. We strongly advise CMS to not further encourage this practice if it implements the use of record review tools, which run the risk of adding to provider burden and burnout. Below we offer more detailed thoughts on selected RFI questions.

We hope our comments are helpful as you gather more information in this important area and as we advance towards the shared goal of utilizing informatics to improve health care. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Enclosed: AMIA Responses to Selected CMS RFI Questions:

[1] https://www.amia.org/sites/default/files/AMIA-Response-to-CY2020-PFS-NPRM-Response.pdf

CMS Question	AMIA Member Response(s)
AI Medical Record Review Tools in Medicare FFS	
1. Do AI medical record review tools exist that can read a medical record and determine whether it is in compliance with a set of coverage guidelines for a given item/service? a. Who should have access to AI medical record review tools? Providers and suppliers, clearing houses, CMS contractors, and/or others? b. Under what circumstances should they access AI medical record review tools? At any time? Before an audit? During an audit?	Industry is still in early efforts with AI and ML. For example, there are increasingly more natural language processing (NLP) tools that can review notes and give guidance for documentation. The challenging part, however, of a medical review tool is that the current tools often focus on the note itself and what is documented, rather than the processes of caring for a patient (e.g. what orders were placed, what diagnoses are being addressed, what medications were given, what labs and imaging were ordered, etc.). Tools are currently being used by health systems to optimize their documentation to reflect what they actually did to care for a patient and the diagnoses of the patient to better reflect the patient severity and need for certain services. If we could use AI tools to extract this information directly from the EHR or from provider notes, it could save some work, but may also increase the amount of documentation needed by a provider. As for access to such tools, we believe that it should be governed by similar privacy and security rules and regulations currently in place for accessing medical records.
2. If AI tools were available that could review records in advance of filing Medicare claims, which we refer to as medical record self-checking services, would providers and suppliers use these tools? a. If the tools were available, what conditions would need to be present for providers and suppliers to actively choose to use the tool?	If AI tools were available, we expect that health systems would use the tools to attempt to improve efficiency in obtaining qualifications and mitigate risk of Medicare audits. If the tools were reasonable to access and seamlessly integrated into the provider's workflow, then they would also want to know in advance of filing a claim. The challenge would be assessing how this review would impact current workflows and documentation practices. There is a possible danger if care decisions or documentation change based upon reimbursement information.

3. If providers and suppliers could access AI medical record review tools to allow for medical record self-checking, where should the AI self-checking service be deployed? At the payer site? In the provider or supplier's EHR? In a secure cloud environment? a. How feasible would it be to deploy AI medical record review tools at the premises of a Medicare review contractor? b. How feasible would it be to deploy an AI medical record review tool at a provider or supplier's local EHR site? c. Should such AI tools be able to be fully integrated into health IT products, such as Office of the National Coordinator for Health Information Technology (ONC) certified EHRs, or would providers and suppliers prefer review tools to exist separately and extract data from multiple sources (e.g. certified health IT, data registries, data repositories, warehouses)? d. Would the use of such AI tools reduce provider/supplier burden if the	Where the medical record review tools are deployed will depend upon whether CMS endorses/contracts with one particular review tool, or if it works with ONC to specify certain functionalities such a tool would need to have, so that they can function similarly for different end users. For example, a Medicare review contractor will have a very different process for receiving/reviewing medical records than a provider or supplier. We believe that it may feasible to deploy medical record review tools at the provider or supplier's site, but once again, we stress that workflow integration is important. As such, the most useful place to have tools like this would be imbedded in the EHRs, with an automated process to have this received and reviewed by the Medicare review contractor. CMS should partner with ONC to make this functionality a part of the Certification program once the technology has been rigorously tested enough to ensure that it would not increase provider burden. While medical record review tools have potential to reduce burden in the long-term via fewer rejected claims and claims audits, this would depend wildly on the amount of times the rejected claims or audited claims are eventually reversed. We caution that an excessive focus on documentation may actually lead to increased documentation, as providers/health systems seek to mitigate the risk of rejected claims.

tools reduce rejected claims and claims audits?	
4. CMS believes that one mechanism to help decrease Medicare improper payments would be to increase the number of claims reviewed before payment. Could current AI medical record review tools enable the review of more claims without increasing provider burden?	A key to decreasing provider burden is to simplify rules or shift away from documentation being the way to determine payment. We are concerned that using AI medical record review tools to increase direct feedback to providers about how they need to improve their documentation to better reflect what they did will lead to even more focus on documentation and eventually more provider burnout.
5. What are the benefits, drawbacks, and even potential unintended consequences of using AI medical record review tools?	The medical record must be created and the timing of this process varies across providers. The tool would not be able to be used until the documentation is created. This is especially true for inpatient admissions, where discharge summaries may be created up to 30 days post-discharge. Another potential unintended consequence is that documentation is created from the financial perspective based upon feedback from the AI tools. Providers must still be able to document all necessary information regardless of financial aspects. If provider documentation is strongly influenced by AI tool feedback, their dissatisfaction may increase.
6. Are there any other ways in which AI could enhance our program integrity efforts?	• AI medical record review tools should be used to shift us away from documentation focus for payments to a more value-based payment system with focus on outcomes and the actual services delivered. One potential area where AI could assist is for prior authorizations. There could be a way to set up prior authorization exports from each EHR for the most common items requiring authorization. The impacts of allowing or not allowing certain procedures, medications, and interventions could then be measured to guide how to regulated these items in the future.

	• It may also be feasible for automated approaches to assist human reviewers by searching for key terms, phrases, or diagnostic codes and present that information to the reviewer to assist in decision making to reduce time spent in navigating charts. We will note, however, that such approaches will never get to the heart of the difficulties with documentation review and the degree of associated provider burden. • If tools were available within EHRs that allows rapid real-time checks and documentation for allowable codes and rapid real-time pre-authorizations of medications without extra steps, extra log-ins, extra phone calls, etc., then these would be beneficial and providers would use them. However, even if CMS were to implement such an approach, its helpfulness would be limited unless other payers agreed to use it as well. • One potential area where CMS can use AI and data analytics more broadly would be to identify providers who are engaging in unrealistic levels of billing that could alert CMS to the need for more detailed review. • Finally, we call CMS's attention to the novel work being performed in the clinical decision support (CDS) community. While AI is part of CDS, much of CDS does not rely on AI. In one example, the SHARPS Data Segmentation[2] project demonstrated an application of CDS technology to a different non-treatment domain – patient privacy. Results from this project strongly suggest that AI-based approaches are inherently unpredictable from the point of view of the provider using the system. Compared to deterministic approaches that are predictable and repeatable, probability-based approaches based on context and training data may behave differently depending on context, and may change over time. This can be frustrating for users. A challenge in applying ML classifiers in a multi-provider environment is that as new providers enter the environment, with unique data quality and correlation profiles, the effectiveness of a classifier trained on prior data may decrease, thereby

[2] sharps-ds2.atlassian.net

	requiring re-training. This too can increase burden. The project also found that structured data may not be sufficient, but rather solutions may need to consider narrative text as well, requiring natural language processing. Finally, the project showed that the EHR data made available to the automated CDS tool (such as an HL7 CDA document) may only be a summary and may not contain all the relevant information needed for a decision.
Questions for Health Care Providers and Suppliers	
21. If AI tools were available, would you use them? If you would not use the AI tools, why not? Please include the specific concerns. If you would use AI tools, please explain how the AI tools would benefit your operations.	If these tools were sufficiently developed and available, then we believe that providers would use them to mitigate audit risk, and even more so if they made them more efficient.
22. For which items/services would it be most helpful to you and your patients to have a provisional Medicare coverage decision before the item is delivered or service is rendered?	Procedures and surgeries would be the most important area, followed by durable medical equipment (DME) and medical approvals. Lab tests, imaging and other tests, and prescriptions would also be especially helpful.
23. Are there key factors, themes, and/or lessons related to AI tools that should be considered?	We note that AI tools are only as good as the data they can see and the rules that govern them. They do not fix the lack of organized data or the complexity of the rules. Having more standardized data and simplified rules will make health systems spend less money on how do document and obtain approval as they care for patients.

24. What metrics should be used to assess the effectiveness of AI tools in the review of medical documentation?	Potential metrics include: number of documentation edits that are required, time from request to coverage review to delivery of service, documentation burden on providers (i.e. time entering materials), documentation burden on staff (i.e. time entering materials), effect on approval of a given service, effect on value of care delivered, and effect on patient outcomes.
25. As a provider or supplier, would you be willing to pay an additional amount for your EHR vendor to connect to AI tools?	This will depend highly on the outcome of the tools. If it brings efficiency, then yes. If it will be needed in order to get reimbursed for the services then also yes (potential increased burden aside). However, if it only increases the burden on providers and care teams to document more, does not provide efficiency, and is not required, then providers will certainly not pay more for AI tools in the EHR.
Documentation Requirement Repositories	
27. Initial feedback from providers indicates overwhelming support for look-up services and a desire to have all documentation requirements available for every service immediately. However, CMS recognizes there are limitations and we would need a phased approach. What do you believe a phased approach would look like? Should we start with the services/items that require prior authorization? All Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)? Another approach?	AMIA agrees with a phased approach, but recommends first defining the objective of a documentation requirement repository. This will help inform the various phases and approach of the work. It would be ideal if the repository outlined perspectives of the documentation requirements, as providers are asked to document from a variety of perspectives, such as for clinical registries, quality reporting measures, and reimbursement support, along with continuity of patient care. The same documentation is asked to support all the various aspects, so outlining the role of this repository in line with other documentation requirements is key before selecting specific services. CMS should then begin with DME and services/items that require prior authorization. Within those two categories, we believe it would be best to automate the ones where the rules are most clearly understood and the data to help approve those decisions is discreet and easily accessible in an EHR. Medication approval would be another important area to consider. An additional approach to consider is addressing the seamlessness of transmission of authorization information. For example, when a medication order is submitted that requires prior authorization under Medicare Part D, it should be immediately apparent

	to the prescriber. Currently, it is submitted via the pharmacy, who must contact the provider if the medication is rejected, who then has to call the pre-authorization number to get a code to enter into the CoverMyMeds website. The provider then has to receive a fax that must be re-faxed to the pharmacy and then the medication is sometimes is still not authorized immediately in the prescribing system. This leads to multiple calls to the patient and the pharmacy and gaps in treatment. Additionally, when a different medication is suggested during the pre-authorization process, but also requires pre-authorization, the prescriber should not have to go through all of the steps all over again.
28. Are there effective consumer-facing smart phone apps that allow a patient or family member to have greater insight into what items/services a provider might order and the payer's prior authorization process, including specific documentation requirements?	Assuming the current state of affairs, it would be useful for patients to be alerted when ordered medications, tests, or other services require pre-authorization or are rejected so that they can follow-up accordingly with the provider, pharmacist, etc. It would be helpful to have a way for the patient/family to file appeals directly through the phone application as well as file complaints directly with state insurance departments for denials of services that compromise safety. Ideally, such an app should be integrated with patient portals.
Data Analytics and Data Systems	
33. What data analytic tools and technologies exist that would help CMS enhance the FPS?	Medical Decision Making (MDM) solutions that would help to identify patients by a unique identifier and have a way to share information across health systems would be an excellent tool to help deliver care. This would also allow the FPS to track an individual patient across multiple health systems. Additionally, automating the processes for turning in approval information and working with EHR vendors to standardize their EHRs to pull needed information into the report that would be sent to process need would be useful. Finally, direct interface from each EHR to a national tool with automated movement of information would be the most efficient way to setup this process. This being said, the data analytic needs and objectives should be outlined prior to settling on a specific tool or technology.

34. What data analytic tools and technologies exists that would allow CMS to ensure legacy data systems can work quickly and seamlessly to identify and address program integrity needs and opportunities without creating new data systems?	Based upon the objectives of data analysis, an outline of current data structure as compared to desired data structure would identify what tools and technologies are in place in the industry. The key would be to help do the mapping between the major vendors and the automated CMS process, instead of leaving it to each organization to do it themselves. Providing tools that help each vendor easily update their systems to send the data to the CMS system efficiently and accurately will be key. Simplifying the process and rules as much as possible before implementation of an automated process is also strongly encouraged.