AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Center for Program Integrity Request for Information on Using Advanced Technology in Program Integrity

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity's Request for Information on Using Advanced Technology in Program Integrity.

- *How CMS can better use emerging technologies such as Augmented Intelligence (AI) to ensure proper claims payment, reduce provider burden, and overall, conduct program integrity activities in a more efficient manner?*

The AMA strongly supports federal and state policies that promote AI applications in health care that advance the quadruple aim and equity. Specifically, AI systems with health care applications should enhance the patient experience of care and outcomes, improve population health, reduce overall costs for the health care system while increasing value, and support the professional satisfaction of physicians and the health care team. Such systems should concurrently promote equity and guard against reinforcing structural inequality or new disparities. It is an AMA priority that there is appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI. Ultimately, the policies developed by the Administration should facilitate the design of high-quality and validated AI systems—particularly those that will be used in health care.

The development of AI tools must integrate the perspective of practicing physicians into the development, design, validation, and implementation of health care AI. Accordingly, the AMA urges CMS to promote development of thoughtfully designed, high-quality, clinically validated health care AI that:

- Is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- Is transparent;
- Conforms to leading standards for reproducibility;

- Identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
- Safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

Finally, AMA policy provides that we are to advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI. To that end, we would stress that all of these should be directly addressed by CMS as priority areas for developers of AI program integrity tools as these represent a clear statement of what a key end-user requires as essential for the adoption of AI systems—particularly ML systems that involve overseeing clinical practice.

Risk of Bias and Adverse Discriminatory Impact

The AMA also strongly urges that any use of AI systems that utilize data-based systems (including continuous learning systems) have a process for ascertaining adverse discriminatory impact. Any government funded or supported system must not contain prohibitions on independent researchers evaluating the algorithm for safety, efficacy, and equity—even if not directly deployed into clinical practice. The importance of this as a central priority is demonstrated by the recent analysis of a commercial prediction algorithm developed (reportedly by Optum) and sold to a number of health systems and impacting millions of patients, which researchers concluded exhibited significant racial bias.[1] The algorithm reportedly explicitly excluded evaluation of race, but rather evaluated costs of care. Because Black patients access care less often than patients of different races (for a variety of reasons), they have fewer costs associated with their care. Accordingly, the algorithm was less likely to flag Black patients to receive interventions that would reduce readmissions. The researchers concluded that "[u]sing traditional metrics of overall prediction quality, cost seemed to be an effective proxy for health yet still produced large biases." This is particularly relevant in the context of this RFI and the use of claims data to evaluate program integrity.

Nomenclature

The AMA has prioritized engagement with standard-setting bodies, including, but not limited to those focused on the health care sector. We strongly support a national strategic engagement plan that assists standard-setting bodies and stakeholders alike to drive consensus to the greatest extent practicable of terminology and nomenclature in this area. In particular, the AMA urges the Centers for Medicare & Medicaid Services (CMS) to work closely with National Institutes of Standards and Technology (NIST) and the Food and Drug Administration (FDA) and engage other federal agencies responsible for federal health programs such as the Veterans Health Administration, to support work among standard-setting bodies that will produce consistent nomenclature, definitions, and terminology. We are concerned that various federal agencies will define and use critical terms differently which will sow confusion, undermine end-user transparency efforts, and undermine safety. In health care the consequences of the foregoing can create new risks and compromise patient health outcomes, create or exacerbate inequities, subject physicians to liability, or drive unnecessary costs.

[1]Obermeyer et al. *Dissecting racial bias in an algorithm used to manage the health of populations*, Science 366, 447–453 (2019) 25 October 2019

It would be helpful if CMS issued, as subregulatory guidance, key terms of importance such as machine learning, natural language processing, and computer vision to ensure that stakeholders understand the range of terms that exist.

AI Medical Record Review Tools in Medicare Fee-For-Service

- *Who should have access to AI medical record review tools?*

The first step of any ultimately successful privacy framework, legislative or regulatory, places the patient first. Each entity seeking access to patients' most confidential medical information must pass the stringent test of showing why its professed need should override individuals' most basic right in keeping their own information private. Moreover, citizens deserve a full and open discussion of exactly who wants their private medical information and for what purpose. Providers and suppliers should have access to AI medical record review tools to ensure clinical and specialty-specific accuracy and validity before other entities have access to use AI medical review tools. Providers and suppliers should also be able to audit, and review predictions and decisions suggested by AI to confirm their clinical validity and appropriateness.

- *Under what circumstances should individuals access AI medical record review tools? At any time? Before an audit? During an audit?*

Providers and suppliers should be able to access the AI medical record review tools at their discretion. Once the tools are validated, other entities that oversee or manage the data should only have access for an ongoing audit or investigation. CMS should not allow the unfettered access to a patient's EHR information to clearinghouses, CMS contractors, or Medicare Advantage (MA) plans.

The AMA has concerns about how these entities will obtain the clinical information necessary to complete a medical record review. We anticipate that some commenters will suggest that these entities be allowed to pull information out of a provider's electronic health record (EHR) via an Application Programming Interface (API) to promote compliance with coverage and payment requirements while reducing burden on the patient and physician. In fact, some payers are already automatically accessing a physician's EHR for other purposes, either as an elective offering or through contractual requirements. We envision non-provider and suppliers viewing this requirement as a logical use case for "tapping into" a physician's EHR. However, physician practices may not understand that access to these data could lead to selective, discriminatory reimbursement models and intrusion on physician medical decision-making power (e.g., lower reimbursement rates for certain types of care that a physician deems necessary or in the best interest of the patient). Furthermore, physician practices could be priced out of markets because an MA plan determines that they are a "second- or third-tier" option based on the totality of the information in the EHR.

Accordingly, CMS should clearly state that (a) non-providers and suppliers are not entitled to receive information from a health care provider if such information is protected by federal, state, or local privacy law; (b) physicians may use their best judgement in responding to a request for clinical information to the extent allowed by law; and (c) payers may not condition provider participation in a plan based on whether a physician will grant the payer or their designee(s) electronic access to the practice's EHR to fulfill requests related to medical review tools.

- *If the tools were available, what conditions would need to be present for providers and suppliers to actively choose to use the tool?*

As stated above, the following conditions would need to be present for development of thoughtfully designed, high-quality, clinically validated health care AI:

- Designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- Transparent;
- Conforms to leading standards for reproducibility;
- Identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities; and
- Safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

With user-centered design, physicians need a single transparent, consistent, and fair medical review process to reduce administrative burden. CMS can simplify rules and policies for physicians surrounding these reviews and deploying AI tools that apply Medicare and Medicaid payment and coverage policies in a consistent and clear manner. Moreover, minor wording or clinically insignificant documentation inconsistencies should not result in nonpayment or extrapolation of overpayments.

Promoting transparency includes supporting the transparency of data uses by stakeholders, including CMS, payers, and health care providers. Transparency includes disclosure of how information is being shared, who is using the data, what data are being used for, and whether the data are being used for their consented purpose. Integrity of data should be ensured throughout its lifecycle including the collection, creation, analysis, use, storage, distribution, disclosure, or disposal of individual information. For example, CMS could establish an internet portal for consolidating information on program integrity efforts including contractor sampling and extrapolation methodologies.

One of the most important characteristics to make data sets and models well suited for use by AI is requiring federal agencies to establish ethical governance, conscious design, and a learning culture regarding federal data. Establishing this type of federal data strategy, as laid out in the President's Management Agenda, may help increase the accuracy, precision, validity, and reliability of an AI's output, which could potentially increase the output's usability and trustworthiness (e.g., accounting for bias and fairness; transparency and explainability; and robustness, security, and safety).

Moreover, the medical record self-checking services must not be considered an initial determination of payment and a physician must still maintain the ability to submit a claim even when the self-checking service returns a negative response. We also believe that physicians would be more willing to use these types of tools if the tools were deployed in the same manner as existing claim scrubbers. Specifically, that any "checking" occurs before any data leaves the practice or EHR, allowing the physician the opportunity to catch and correct errors. The relationship between physician and the AI tools should be positive providing positive feedback compared to a punitive check on the payer end.

An additional condition that would need to be present for adoption is that the medical record self-checking services algorithm properly captures and considers specialty, patient mix, and site of service and is reviewed by a practicing physician of the same specialty that the physician who is using the self-

checking service. Any standardization in medical necessity criteria across payers will go a long way towards minimizing the number of AI tools a practice needs to implement and contain costs.

- *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?*

Physicians need access to interoperable and usable health IT that is well-integrated into their workflows. The AI medical record review tool should be deployed and integrated into the clinical workflow. Product integration can mean various things. For example, a physician clicking a hyperlink in their EHR to launch a webpage in a separate browser window could be considered "basic" integration. Alternatively, using an API to enable bidirectional information exchange with that same website could be considered "advanced" integration. Both examples allow the physician to enter and access data; however, the level of cognitive burden on the physician may be substantially different. Depending on the use case, launching a new window may be more efficient and cost effective. However, as in the case with accessing Prescription Drug Monitoring Program (PDMP) information, the "window swapping" and hand-keying of information between applications detracts from physician-patient time. As the demand on physician time increasees (along with the influx of data), physicians will require tighter integration with third-party applications and services. A simple matrix comparing EHR products, prevalent third-party systems (PDMPs, state immunization registries, etc.), and their integration level (basic, intermediate and advanced along with a description and examples of each level) would benefit physicians and could be useful in helping to establish a baseline of system-to-system interoperability.

The AMA cautions, however, CMS and the Office of the National Coordinator for Health Information Technology (ONC) from going down the path of regulating technology. We view this concept as a microcosm of what has plagued the EHR Incentive Payment/Promoting Interoperability Program for much of its history: seeking to nationalize a prescriptive activity by leveraging health IT at a granular level. While we acknowledge a degree of benefit from this approach early in the nation's journey towards digitized care, we question its effectiveness and the resulting unintended consequences. Rather than prescribing the use of certain technology and standards, the best approach is for CMS to promote the use of medical review tools with positive incentives and for ONC to focus its efforts on ensuring health IT vendors develop and implement open API interfaces in a standardized and consistent fashion.

- *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?*

The AMA would generally caution against indiscriminately increasing the number of claims reviewed before payment. Instead, CMS should focus on those providers who have demonstrated a propensity to commit fraud or abuse. Otherwise, additional claims review will inequitably affect physicians and other health care professional who are compliant actors, resulting in unnecessary costs to the health care system. Moreover, CMS needs to consider the impact on timely filing requirements when increasing the number of claims reviewed. Private payers are adding prepayment review claim edits that bounce back to the provider before they are accepted into the claims adjudication system. The AMA has heard that this can lead to issues with timely claims filing requirements. If the before payment claim is not accepted by a payer and needs additional information, providers miss the timely filing deadline since the payer never accepted the claim. While Medicare fee-for-service has a one-year filing deadline, many MA plans are

shortening their timely filing requirements.[2] As stated above, having the AI tool in the EHR would be beneficial because the physician could correct errors prior to submitting for pre-payment review and potentially have a payer delay claim submission past the timely filing deadline.

- *What are the benefits, drawbacks, and even potential unintended consequences of using AI medical record review tools?*

The AMA appreciates that CMS recognizes that benefits and drawbacks may exist in using AI medical record review tools. We believe that AI systems generally and Machine Learning (ML) systems in particular may serve as transformative tools that will aid this nation and others around the globe in addressing increasing stress on health care systems at a time when human and financial resources are not likely to keep pace with demand. For example, the AI medical record review tool could reduce burden, ensure quicker payment, and allow physicians to focus on providing care. However, drawbacks may exist including not accounting for undisclosed and unintended biases, including those that exacerbate health disparities. For example, the AI medical record review tool may only be used by certain sophisticated health systems that may have a different patient population than rural or small practices. Thus, if the AI medical record review tool does not account for potential bias in the data, medical review may inappropriately favor medicine being practiced in a sophisticated health system.

A popular tendency exists to see AI as, at best, a form of neutral, "objective" decision-making, a pristine mathematical process that takes only "the facts" into account, independent of human judgment. The statistical process of AI specifically seeks to derive a rule or procedure from a body of data that explains that data or is able to predict future data. Accordingly, an AI derived algorithm "is only as good as the data it works with," yet the data sets on which AI algorithms are trained are created by human agents and are imperfect. The research, patient care, and insurance records available as training data sets for health care AI can be highly variable, reflecting the different purposes for and processes by which they were created. For example, clinical trials systematically include or exclude participants with certain characteristics; patient charts and insurance records capture information only from those individuals who have access to the health care system and rarely contain information about certain variables, such as exposure to environmental toxins. Different data sets focus on different kinds of information to the exclusion of other possible data points, and records capture and preserve information with varying degrees of accuracy. One of the most significant implications for end users of AI systems is that these systems sets can, invisibly and unintentionally, "reproduce and normalize" the biases of their training data sets. In health care, the result can be models that "reflect the conditions only of the fortunate" and yield "an aggregate understanding of health and illness that fundamentally excludes the marginalized" in a way that risks exacerbating existing health disparities.

- *Are there any other ways in which AI could enhance our program integrity efforts?*

AI, like program integrity, has implications across the health care delivery system. AI can help mitigate or exacerbate program integrity concerns. Properly deployed AI can promote proper program gatekeeping, sound payment, effective compliance, and continuous monitoring to help prevent fraud, waste, and abuse. Improperly deployed AI can promote the opposite through nefarious and intentional measures of bad

[2] E.g., Anthem's recent decision to move to a 90 day timely filing requirement in 2020. https://www.doctors-management.com/anthem-is-changing-their-timely-filing-requirements-for-all-plans-including-medicare-advantage/

actors or because the AI was developed on misguided rules or used inappropriate or insufficient data when trained. This improper deployment increases the risk of improper payments and may cause patient harm through improper diagnosis or recommending inappropriate procedures.

Importantly, the AMA believes that AI can enhance efforts by providing responsive feedback loop so that any inappropriate AI guidance identified by providers can be quickly addressed and corrected. If AI is giving incorrect information, a mechanism needs to exist to act on complaints from physicians and adjust programming to correct the problem leading to faulty AI decisions.

Questions for AI Medical Record Review Tool Vendors

The AMA strongly urges CMS to include questions related to the process used by the vendors to test and evaluate the tool for discriminatory impact. In addition, CMS should ascertain whether vendors would attempt to limit access by researchers who would evaluate the systems for discriminatory impact, for example.

Questions for Health Care Providers and Suppliers

- *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.*

As stated above, the AMA will promote development of thoughtfully designed, high-quality, clinically validated health care AI that:

- Is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- Is transparent;
- Conforms to leading standards for reproducibility;
- Identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
- Safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

Thus, the AMA would not promote AI tools that are not focused on patient outcomes, not properly tested, are discriminatory and create or reinforce structural inequality, or have poor privacy and security controls.

The AMA strongly urges CMS to incorporate tying developer goals of any AI tool—including medical record review—to patient outcomes as a foundational requirement. Such a requirement would align with CMS' stated goal of putting patients first. For example, in addition to the data training risks, ML systems conducting a medical review may learn to detect features that are closely associated with a diagnosis, but that are divorced from improvements in clinical outcome. Mirroring a diagnosis or a clinical practice itself does not ensure beneficial patient outcomes. A framework that does not tie clinical outcomes research could lead to AI systems that deviate from outcome-based clinical standards which could be more pronounced for ML.

Testing is a core aspect in the development, validation, and evolution of all technology. As with any technology, AI testing must ensure it meets the requirements that guided its design and development, responds correctly to inputs, performs its functions within an acceptable time, is sufficiently usable, and achieves the general result its stakeholders desire. Testing should also closely resemble operational production environments (e.g., a real-world medical facility), rather than synthetic simulations. To accelerate AI testing, the federal government should ensure federal datasets maintain their approximation of real-world care and practice settings. These efforts should be in coordination with the physician and medical informatics community.

Health care information is one of the most personal types of information an individual can possess and generate. An individual's privacy should be honored unless waived by the individual in a meaningful way, de-identified, or in rare instances when strong countervailing interests in public health or safety justify invasions of individual privacy or breaches of confidentiality. Individual trust in the health care system can only be assured when all entities—including the federal government and its contractors—that maintain an individual's health information have an obligation to ensure the confidentiality of that information and when individuals have autonomy and control over decisions to disclose or retain their personal information. This type of control requires transparency from data holders to empower individual decision-making. Overall, individuals should have appropriate access to their data and physicians should have the tools and controls they need to be good stewards of this information, including their patients' medical record.

The federal government should also mitigate privacy risks as it relates to providing access to federal data. Privacy risks include re-identification of individuals through de-identified (or partially de-identified) data; misunderstanding or disregard of the scope of an individual's consent; individual perception of loss of their privacy leading to a change in their behavior, embarrassment, or stigma resulting from an unwanted disclosure of information or from fear of a potential unwanted disclosure; perceived and real risks of discrimination, including employment and access to or costs of insurance; and law enforcement accessing data repositories beyond their intended scope.

Ensuring security means emphasizing the need for security practices to stay up to date with current and emerging threats to protect data integrity and foster innovation and leverage new technologies to maintain protection.

The AMA believes that CMS should promote the efficient use of data access by providers and patients including open access to appropriate machine-readable public data, development of a culture to share health care data with external partners, and explicit communication of allowable use with periodic review of informed consent. In providing open access to appropriate data, the AMA encourages disclosure of the characteristics of the datasets including the data sources, data collection, and data curation methods accompanied by an assessment of undisclosed and unintended biases resulting from the data-gathering process and any efforts made to mitigate these risks. Accounting for unintended bias in data sets is a central metric of data quality and a key to mitigating the risk of potentially furthering disparities.

- *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?*

Physicians would like to know that they are able to be compensated when providing medical necessary care to patients with coverage for a particular procedure. Pursuit of a provisional coverage decision

should not be the end goal—we should be aspiring to have a Medicare system that is sufficiently transparent and readily accessible enough so that a physician could know that their care will be covered without having to conduct an additional administrative screening process up-front.

Tools that can flag coverage restrictions and documentation requirements at the point of care would significantly improve transparency and address the current opacity in payer rules. For example, the Coverage Requirements Discovery use case currently under development as part of the Da Vinci Project leverages Fast Healthcare Interoperability Resources (FHIR) to present payer coverage information, such as prior authorization requirements, to physicians at the point of ordering. Placing this information into a singular EHR workflow is far more efficient than the current situation in which practices must dig through a myriad of resources and formats currently used by payers to find the data. Similarly, prospectively informing physicians of any documentation required to support payment for a particular service is similarly beneficial. CMS' efforts to centrally house Medicare documentation requirements information in a single website in the Documentation Requirements Lookup Service is a positive first step in easing physician burdens. Ideally, this information would be available in physicians' EHRs and presented at the time of ordering, which is the scenario currently being addressed by the Da Vinci Documentation Templates and Rules use case. While there are still many unanswered questions about how soon this technology will be widely available across physician practices of all sizes, the implementation costs, and how these tools can be deployed while ensuring that only the minimally necessary protected health information is shared with payers, the AMA believes that exposing payers' payment rules and documentation requirements "upstream" in the ordering process and within EHR workflows has the potential to reduce practice burdens by improving transparency.

- *What metrics should be used to assess the effectiveness of AI tools in the review of medical documentation?*

To be effective, physicians need to understand AI methods and systems sufficiently to be able to trust an algorithm's predictions—or know how to assess the trustworthiness and value of an algorithm—as a foundation for clinical recommendations. The challenge may be more easily met with advances in "explainable AI," that is, algorithms that can "explain" to users why a particular prediction is made. Technology to predict the risk of 30-day readmission for cardiac patients being tested by Boston-based Partners Connected Health provides clinicians with a readmission prediction score and identifies the top factors contributing to that score, providing information that is actionable for clinicians. As mentioned above, the AMA stresses the importance of transparency in AI algorithms and again the need for a feedback loop for physicians to report concerns with faulty algorithms and those issues to be quickly addressed/adjusted. Physicians should be able to audit AI output and ensure the machine is providing clinically sound direction

- *As a provider or supplier, would you be willing to pay an additional amount for your EHR vendor to connect to AI tools?*

Physicians need to purchase newer software, hardware, and/or interface capability, placing additional costs on the practice. We are very concerned that connecting to AI tools would require substantial investments in several interfaces and customizations, and that this could also be a significant factor in deterring adoption. Once a product is installed, an EHR vendor typically requires a monthly maintenance fee based on the initial cost of the product. These fees can range from a few thousand to tens of thousands of dollars a month. Additionally, each custom software change or interface needed to meet reporting

requirements contributes to unexpected costs, which burden physicians and divert resources from patient care. These costs will increase exponentially if practices are required to deploy different AI tools to support highly variable payment rules across multiple payers. Moreover, the AMA is concerned that if not properly integrated, the AI tools may fail to improve physician workflow, patient care, and practice needs.

- *What would motivate providers and suppliers to stop using the fax machine to submit medical records under review?*

To reduce physician usage of outdated technology, a secure, efficient, standardized method of submitting appropriate medical records to any and all payers is needed. Too frequently, there are simply not more efficient means for submitting clinical records to a payer in a timely manner that does not involve significant additional work or investment from physicians on the front end. As the AMA has noted in multiple previous comments to CMS, the lack of a standard for electronic clinical attachments serves as an ongoing barrier to the efficient submission of supporting clinical documentation. Without this critical mandate, payers will continue to require a variety of different transport methods and formats for clinical documentation—including the fax machine, which many practices turn to as an undesired default. Without federal guidance on an electronic standard for clinical documentation, health plans, vendors, and provider organizations will be unwilling to invest in the technology to support automated exchange of medical records. While recent developments in FHIR technology and the Da Vinci project may have created uncertainty as the best standard for clinical data exchange, CMS must quickly identify a path forward for the industry. If more data are needed to identify and validate a standard for mandate, then a timeline for pilots, reporting and analysis of those pilots, and decision on a standard should be outlined. Without this formal plan, the industry will continue in its current limbo, with many players unwilling to invest in nonmandated technology.

Documentation Requirement Repositories

- *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?*

The AMA supports the use of look-up services—including the Documentation Requirement Lookup Service—insofar as they provide easily accessible, low cost, integrated, and usable information within a physician's workflow. Independent of the service/item, documentation requirement repositories should be built to enable health information technology (health IT) systems (e.g., EHRs) to query and pull requirement information using consensus-driven and balloted data exchange standards. Repository development and maintenance costs should be covered by health plans. Health plans should, to the greatest extent possible, align on a common suite of standards, technology, protocols to limit "one-offs" or unnecessary uniqueness in repository design. Of note, proprietary look-up services that are unique to specific health plans are not nearly as efficient or useful to physicians as technology that is embedded within EHR workflows and provides information about coverage restrictions or documentation requirements at the point of ordering or prescribing. Additionally, health plans should be restricted from requiring physicians to use repositories and should refrain from including "repository use" in physician contracts or conditions of participation. Health IT developers should be included in repository design to

reduce cost and complexity and to ensure timelines are aligned with other health IT development priorities. Further, physicians and other providers should be included to reduce downstream burden on the end-user community.

- *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?*

We are aware that some health plans and benefit managers offer information about benefits and coverage restrictions such as prior authorization in patient portals and/or consumer-facing phone apps. However, we are unaware of any such patient-facing tools that flag documentation requirements and are unclear as to why consumers would need this information, as clinicians are responsible for creating and submitting such data to payers. Moreover, we must underscore the importance of patient-physician discussions in the selection of appropriate therapy. The implication that a patient might be using a payer app to determine the most clinically appropriate treatment without first consulting with his/her physician is concerning. While the AMA fully supports patients having access to complete and accurate information regarding their benefits and any coverage restrictions, including prior authorization, it is paramount that any such technologies not direct patients toward a particular treatment without first discussing it with their physician. The physician and patient can work together to select the best therapy based on the patient's unique clinical situation and medical history, using any payer-supplied benefit information to ensure that any documentation requirements are fully met.

Advanced Technologies for CMS to use in Medicare Advantage and for CMS Contract Level Risk Adjustment Data Validation (RADV) Audits

The overriding priority should be to minimize the administrative burden on physician practices and ensure patients are receiving necessary care. The AMA urges caution until a range of systems are identified and the implications for burden on physician offices. The purpose of AI systems should be streamlining burden, not simply optimizing the payments made to MA plans. Any program considered by CMS should advance the quadruple aim and equity.

The AMA recognizes the potential benefit of reducing administrative burden associated with RADV audits through improved record access. However, we have concerns about whether excessive data access could potentially impact patient privacy or physician autonomy.

Historically, payers have only had access to specific clinical information. Physicians have acted as stewards to determine what information is necessary for each individual to be covered, for the physician to be paid, or in response to an audit. However, automated access to the EHR would potentially remove that stewardship and grant the payer access to information in the EHR beyond what it needs for a particular transaction or for auditing purposes. This could have negative downstream consequences for patients and physicians. Tools used to collect medical records for auditing may not limit the use of data beyond the stated purpose. Given the current state of technology, automated record retrieval can function as "select all and copy" function, gathering bulk information irrespective of need or purpose. Repurposing extracted medical records may become increasingly frequent without further development and controls around data extraction. The AMA has significant concerns about whether excessive data access will lead to increased prior authorization and patient profiling—limiting coverage and access to care. Even when

patients already have coverage, there are examples of payers making coverage decisions based on patient information that neither the patient nor the patient's physician knew the payer was receiving.[3]

We caution unintentionally promoting payers "tap into" a physician's EHR. Physician practices may not understand that access to bulk data could lead to selective, discriminatory reimbursement models and intrusion on physician medical decision-making power (e.g., lower reimbursement rates for certain types of care that a physician deems necessary or in the best interest of the patient). Furthermore, physician practices could be priced out of markets because a payer determines that they are a "second- or third-tier" option based on the totality of the information in the EHR.

Accordingly, CMS should clearly state that (a) payers are not entitled to receive information from a health care provider if such information is protected by federal, state, or local privacy law; (b) physicians may use their best judgement in responding to a request from a payer for clinical information to the extent allowed by law; and (c) payers may not condition provider participation in a plan based on whether a physician will grant the payer electronic access to the practice's EHR for auditing or another purpose.

Provider Enrollment

- *CMS affiliation and ownership information is presently self-reported today. What data sources are available for CMS to collect and potentially enhance the Advanced Provider Screening System (APS), so that CMS can examine and validate affiliation information and/or ownership data?*

In addition to CMS seeking additional data sources for affiliation and ownership information, physicians also need this information for disclosable events in reporting affiliations. When fully implemented, the Program Integrity Enhancements to the Provider Enrollment Process Final Rule will significantly increase the administrative burden on physicians by requiring the indefinite maintenance of records for all disclosable events for current and the previous five years' affiliations. For example, a physician would need to find out and disclose an affiliates' payment suspension from 35 years ago. This example is particularly troubling because no publicly searchable database exists for certain disclosable events. Thus, providers are left with little capability to verify with a third party whether a past or current affiliation has a disclosable event and may need to conduct background checks. We believe that it is unreasonable to expect physicians, particularly solo practitioners, to have the resources to accomplish this level of due diligence. Furthermore, checking for affiliations may take time away from providing patient care.

Requiring all providers and suppliers to report their affiliations would be a significant step backwards in the Agency's efforts to provide regulatory relief and to put patients over paperwork. While CMS' estimates of the cost-avoidance savings would be $10-$30 billion over five years, CMS also states that it would have only used this authority approximately 838 times, or for .05% of the providers and suppliers over a five-year period. Accordingly, the AMA strongly believes that the affiliation requirements are overbroad and impose additional burdens on physicians. Rather than focusing on those providers who have demonstrated a propensity to commit fraud or abuse, the requirements inequitably affect physicians and other health care professionals who are compliant actors, resulting in unnecessary costs to the health care system.

[3] Marshall Allen, *You Snooze, You Lose: How Insurers Dodge The Costs Of Popular Sleep Apnea Devices*, National Public Radio and ProPublica (Nov. 21, 2018), available at https://www.npr.org/sections/health-shots/2018/11/21/669751038/you-snooze-you-lose-how-insurers-dodge-the-costs-of-popular-sleep-apnea-devices.

Data Analytics and Data Systems

The federal health care programs and law enforcement are moving to a fraud prevention model that utilizes data analytics to identify aberrant claims in real time, and cross references such claims with other data sets to recognize fraudulent or abusive activity. This focused, streamlined approach—if clinically-informed and carefully developed—has the potential to prevent funds from being fraudulently misappropriated from the health care system.

Importantly, data analytic systems also have the potential to decrease the administrative burden that has traditionally accompanied the "pay and chase" model. The concept involves identifying and preventing fraud and abuse on the front end, rather than through post-payment activities, which have historically inequitably impacted many non-fraudulent physicians and other providers. For example, CMS expanded its Targeted Probe and Educate program to all jurisdictions. The AMA believes this is a step in the right direction. We look forward to working with CMS as it moves forward to implement this program to ensure that it is done in a thoughtful manner.

Implicit in the success of data analytics in fraud identification is the ongoing clinical input of physicians. Such expertise is required to enable data analytic systems to operate properly and reach a zero false positive rate. Medical claims data analysis requires complex clinical knowledge. Thus, the review and analysis of such claims necessitates the clinical lens of physician education and training.

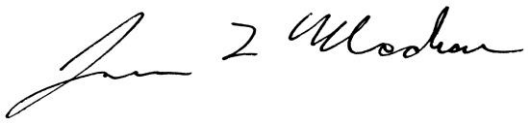
By using data analytics, CMS can improve feedback to and training for providers, thereby improving the accuracy and validity of reporting. Furthermore, data analytics can accurately identify poor performers to target for outreach and assess future performance.

The AMA recommends that CMS:

- Formalize a process for ongoing, independent clinical review of its data analytics system;
- When conducting oversight activities, identify providers with questionable patterns of claims and prioritize providers that most warrant further review;
- Avoid using automatic threshold-based criteria in determining when and whom to review; and
- Use previous experiences with fraudulent providers to create and continuously improve models to prevent future misconduct.

We thank you for the opportunity to provide input on this request for information. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



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