January 28, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Submitted electronically via healthit.gov

Re: Office of the National Coordinator for Health Information Technology (ONC), Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health ITs and Electronic Health Records (EHRs)

Dear Dr. Rucker:

On behalf of more than 44,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology (ONC) on the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health ITs and Electronic Health Records (EHRs). We also fully support and echo the comments of the American Medical Association (AMA). Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

The 21st Century Cures Act requires HHS to outline a plan for reducing regulatory and administrative burden related to the use of health IT and electronic health records (EHRs), specifically requiring HHS to: (1) establish a goal for burden reduction relating to the use of EHRs; (2) develop a strategy for meeting that goal; and (3) develop recommendations to meet the goal.

In response, HHS and ONC (collectively ONC) have issued this report in which they outline three primary goals based on stakeholder engagement: (1) reduce the effort and time required to record information on EHRs for health care providers during care delivery; (2) reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations; and (3) improve the functionality and intuitiveness/ease of use of EHRs. Through their stakeholder engagement, ONC also identified four key issue and challenge areas: (1) clinical documentation; (2) health IT usability and the user experience; (3) EHR reporting; and (4) public health reporting. Within each of
these challenge areas, ONC identifies corresponding key strategies and recommendations. We have commented below on key strategy areas of importance to our members.

**Clinical Documentation**

*Strategy 1: Reduce regulatory burden around documentation requirements for patient visits.*

**CMA Recommendation:** CMA strongly opposes the proposed collapse of the E/M office visit codes from eight to two for both new and established patients, and disagrees that the added documentation reduction from the code collapse-single payment proposal as envisioned by CMS will be realized.

CMA appreciates the Administration’s focus on reducing physician’s administrative burden and physician burnout. As noted in the report, unnecessary clinical documentation is a common challenge faced by physicians. The report lays out the documentation burden reduction initiatives finalized by CMS in the calendar year (CY) 2019 Medicare Physician Fee Schedule final rule (2019 final rule) as key to the Administration’s efforts to address excessive clinical documentation. CMA agrees that the policies finalized for CY 2019 are extremely positive and will reduce unnecessary documentation. We also appreciate that CMS has recognized the ongoing work of the AMA and medical specialty societies including CMA on E/M documentation burden and postponed the implementation of any coding and payment-related changes to E/M visit services until 2021.

CMA strongly opposes the proposed collapse of the E&M office visit codes from eight to two for both new and established patients. According to a detailed analysis by the AMA, this change would result in significant payment cuts of 4-20% that would harm physicians in specialties that treat the sickest patients, as well as those who provide comprehensive primary care. It jeopardizes access to care for the chronically ill and patients with complex conditions – those most in need of comprehensive care management. Even with the proposed add-on payments for primary care, designated specialties, and prolonged visit services, most California physicians report to CMA that they will still experience inappropriate payment cuts and potentially, increased documentation burdens. Valuing the services provided to more complex patients the same as those provided to much less complex patients is fundamentally flawed and inconsistent with the Resource-Based Relative Value Scale foundation of the Physician Fee Schedule.

Most California physicians are seeing an increase in an aging patient population with multiple chronic conditions. In some California counties, Medicare-Medicaid dual eligible patients represent 30-40% of the total Medicare population. Under this proposal, physicians will not be incentivized to treat complex, costly patients. Many physicians will stop participating in Medicare altogether and access to care will suffer for the millions of California seniors.
For the last two decades, Medicare payments have failed to keep pace with the rising costs to operate a medical practice. Measured in real dollars, Medicare physician payments have decreased by 25% since 2001. These declining payments have forced many physicians to reduce the number of Medicare patients they can accept. The E&M restructuring proposal will exacerbate physicians' ability to appropriately care for their patients.

Moreover, while CMS has given relatively favorable value to the collapsed initial and follow-up codes, we are concerned that private payers will adopt the coding changes without commensurate valuation. CMS asserts that documentation burden would be substantially reduced and time available for patient interaction increased by the streamlined visit level selection and minimal medical record entry incorporated into the office visit reporting process. CMA strongly disagrees that the added documentation reduction from the code collapse-single payment proposal as envisioned by CMS will be realized.

**Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.**

**CMA Recommendation:** CMA supports standardizing and automating prior authorization processes to reduce the burden on physicians, as well as improving real-time access to payer requirements for prior authorization.

Prior authorization processes present an ongoing burden to physicians that could be alleviated by more standardized health IT process. The prior authorization processes do not align by payor. Each payor has its own list of CPT codes that require authorization and its own form specific to that CPT code that must be completed to initiate the authorization process. While there are statutory timeframes in which payors must make a prior authorization determination, some payors do not meet those deadlines consistently. The current system imposes a significant burden on physician practices. In a physician survey conducted by the AMA on prior authorizations, 84 percent of physicians said the burdens associated with prior authorization were high or extremely high, and nearly the same number of caregivers (86 percent) said burdens associated with prior authorization have increased during the past five years. Furthermore, the survey states that, “every week a medical practice completes an average of 29.1 prior authorization requirements per physician, which takes an average of 14.6 hours to process -- the equivalent of nearly two business days.” To keep up, 34 percent of physicians said they rely on staff who work exclusively on data entry and other manual tasks associated with prior authorization.\(^1\)

Time spent requesting and documenting prior authorizations can also delay the delivery of timely treatment to patients, resulting in worse outcomes for the patient. A 2017 AMA survey found that 90 percent of physicians agree that prior authorization programs negatively impact patient clinical outcomes. The prior authorization process delays patient access to...

---

necessary care. The survey found that 78 percent of physicians believe that prior authorization can, “sometimes, often or always lead to patients abandoning a recommended course of treatment.”

The current process for prior authorization imposes a significant burden on physician practices. However, improvements to the process such as establishing a standardized electronic prior authorization process that physicians can use in addition to other methods can create some efficiencies in the process. The use of standardized electronic prior authorization transactions saves patients, providers and utilization review entities significant time and resources and can speed up the care delivery process. Policy changes such as eliminating prior authorizations for medications and procedures that have been approved a majority of the time would also alleviate some of the burden and ensure timely treatment to patients. The American Medical Association and Anthem recently issued a joint statement announcing that they will seek to identify and collaborate on solutions that drive a high-value experience for patients, physicians, other health care professionals and health plans. One of the areas for collaboration that they announced is to streamline and/or eliminate low-value prior-authorization requirements and implementing policies to minimize delays or disruptions in the continuity of care.

We believe it would be valuable to streamline the processes related for prior authorization of services which can delay critical patient care. With the appropriate EHR infrastructure and data elements in place, physicians can ensure that patients receive necessary care faster without having to first go through a time-consuming prior authorization process. HHS should also work with payers and EHR vendors to allow for real-time, searchable information about what is covered under a patient’s insurance, including any prior authorization requirements. Using health IT to enable transparency among payer process can help reduce burdens on physicians and ensure better access to care for patients.

**Health IT Usability and the User Experience**

*Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.*

**CMA Recommendation:** ONC should require EHR vendors to design systems that are usable based on the needs of medical practice in order to receive CEHRT approval, and impose penalties when these standards are not met.

Physicians report spending an increasing amount of time completing clerical work rather than being able to focus on their clinical practice.² One study found that only 27% of

---

physicians’ time is spent with patients, while nearly half is spent on EHRs or other desk work. Nearly three-quarters of physicians report that EHRs have increased the total number of hours worked and are contributing to physician burnout. EHR systems have also not necessarily reduced administrative costs, with these costs accounting for at least one-quarter of professional revenue for certain patient encounters. Finally, physicians have reported that their EHR systems have hidden fees, insufficient customer support, and lack interoperability.

When physicians and their practices spend an excessive amount of time on administrative tasks, their time and attention is diverted from the primary purpose of any medical practice: providing direct health care services to patients. A study on the allocation of physician time in ambulatory practice found that physicians spend 33.1 percent of their work hours on direct clinical face time with patients and staff, versus 49.2 percent of their time completing clerical work or EHR-related tasks.

One factor increasing the time spent on clerical tasks is the poor design of EHRs which fail to reflect the nature of clinical work and detract from rather than assist in physician’s practice. ONC should engage physicians and other stakeholders to improve the design and usability of EHR is a way that comports with physical practice. ONC should also make sure that these concerns are reflected in its certification process.

Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

CMA Recommendation: ONC should strengthen CEHRT interoperability standards and utilize enforcement mechanisms to secure compliance from EHR vendors.

In the past few years, CMA staff has received an increase in complaints from physicians about their EHR vendors. The complaints have largely been about the hidden costs of maintaining and upgrading their EHR system beyond the implementation costs as well as lack of sufficient customer support. Many EHR vendors charge costs above and beyond the initial expense of implementing an EHR. Physicians report that they are forced to pay these additional costs because without these software upgrades, they are unable to meet meaningful use and would then be forced to return incentive moneys they have already received and used to implement the EHR. Furthermore, the ONCHIT Program notes that

3 These doctors think electronic health records are hurting their relationships with patients, PBS NEWS HOUR (Juy 21, 2017), available at https://www.pbs.org/newshour/health/doctors-think-electronic-health-records-hurting-relationships-patients.
some EHR vendors likely participate in opportunistic pricing, suggesting that the high cost of switching technologies and lack of upfront information about the costs may lead to the exploitation of customers (e.g., CA physicians). As such, increased oversight over EHR vendors by state and federal regulatory agencies is necessary.

In addition to cost, physicians have reported that their EHR systems lack interoperability and bi-directional capability. The ONC’s recent release of the Interoperability Map shows a promise of the federal government to implement guidelines as it relates to interoperability. However, the roadmap lack enforcement measures to ensure EHR vendors adhere to the guidelines.

While federal law bans information blocking and establishes a framework for the certification of EHR technology (CEHRT) that includes compliance with certain standards, there has not been proper enforcement under federal law to ensure that EHR systems comply. In addition, when CEHRT vendors do not meet these standards, it’s the providers left facing disruptions in service and payment penalties when they are then unable to meet meaningful use criteria and promoting interoperability requirements under the EHR Incentive Program and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Therefore, there is currently little incentive for vendors and developers to meet and keep up with updated laws and standards once their product is "certified" by the ONC.

Interoperability has also been shown to reduce or eliminate unnecessary and duplicative diagnostic workups, improve medication reconciliation, synchronize the use of drugs, reduce chances for adverse drug reactions, reduce or eliminate fraud and waste, and decrease abuse trends with particular drug classes such as opioids.

The West Health Institute (WHI) recently testified to Congress and released an estimate that system and device interoperability could save over $30 billion a year in the U.S. healthcare system alone, while simultaneously improving patient care and hospital safety. A recent National Health Information Exchange and Interoperability Landscape report also found that 80 percent of providers saw increased efficiency and 89 percent saw improved care quality by using electronic data exchanges.

Yet with all these benefits, we’re still no closer to nationwide interoperability. In fact, there has been scant progress, according to a recent Health Affairs report. Just 29.7 percent of hospitals

---

7 See ONCHIT website at www.healthit.gov/policy-researchers-implementers/interoperability.
nationally engaged with finding, sending, receiving and integrating patient data from outside providers. And that’s only up about 5 percent from 2014.\textsuperscript{10}

Thus, it is important that existing and ongoing efforts to increase CEHRT standardization are enforced to enable the secure transfer of health data and achieve meaningful interoperability between disparate systems. In additional to strengthening the CEHRT standards, ONC should utilize enforcement mechanisms to ensure vendors are complying with interoperability requirements and penalize those who fail to comply.

\textit{Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.}

\textbf{CMA Recommendation:} ONC should require greater consistency across EHR systems to encourage sharing of clinical data.

As the use of EHR systems has become common with the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, there has been increased data sharing between individual health care providers and within health systems and organizations. Oftentimes, however, systems don't utilize consistent standards and, therefore, are not able to communicate with other systems.\textsuperscript{11} Even when specific data fields can be matched with similar data fields in another system, the products are designed with different screen layouts that display information differently. This is particularly challenging and burdensome for clinicians who work at multiple health care institutions using different EHRs.\textsuperscript{12} Therefore, unlike in other industries where computerization has made work easier, deployment of EHRs in their current state—coupled with growing requirements for high-quality reporting and regulatory compliance—only create additional work and exacerbate clinician burnout.\textsuperscript{13} ONC should encourage vendors to consistent standards for clinical data to allow for communication and sharing across systems.

\textbf{EHR Reporting}

\textit{Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.}

\begin{itemize}
  \item Interoperability and Health Information Exchange, HIMSS (December 2018) available at https://www.himss.org/library/interoperability-health-information-exchange
  \item Procuring Interoperability, Pronovost et al (2018) National Academy of Medicine
\end{itemize}
**CMA Recommendation:** Simplify and reduce the quality measure reporting physicians are required to complete for federal programs.

Quality measures do not align among all payors which means physicians are required to report multiple quality measures in different ways to different entities. This imposes significant burdens on physician practices. A recent study\(^{14}\) indicates physicians and their staff can spend upwards of 15 hours per week dealing with quality measures with different payors. The physician time alone spent dealing with quality programs is estimated to be enough time to care for approximately nine additional patients and the staff time spent is incredibly costly to practices.

An example of a quality program that continues to be a time-consuming burden is the Medicare Access and CHIP Reauthorization Act of 2015. In 2015, the U.S. Congress passed MACRA which reformed the way physicians and other clinicians are paid under Medicare Part B. MACRA repealed the Medicare Sustainable Growth Rate (SGR) formula and replaced the Medicare reporting program (the Physician Quality Reporting System (PQRS), the Medicare Electronic Health Records (EHR) Incentive Program, and the Value-Based Payment Modifier (VM)) with the Quality Payment Program, which is made up of two payment tracks: the Advanced Alternative Payment Models (APM) and the Merit-based Incentive Payment System (MIPS). While MACRA aims to provide stable payment updates, reduce the quality reporting program burdens, reinstate bonus payments, and incentivize innovative, physician-led alternative payment models, there are still areas that pose significant burdens to physician practices. CMS has subsequently published several regulations detailing the specifics of the Quality Payment Program under MACRA.

In 2019 final rule, CMA was extremely disappointed that CMS did not reduce the reporting burdens in the MIPS program in a more meaningful way. We certainly appreciate the reductions in the EHR-Promoting Interoperability Category process measures but we would like to request simple Yes/No attestations for the entire category. We oppose the confusing new scoring tiers (gold, silver and bronze) and urge CMS to simplify and overhaul the complex MIPS scoring system consistent with the AMA recommendations. Specifically, we urged CMS to:

- **Significantly reduce the number of Quality measures;** restore the topped-out quality measures to give physicians a sufficient number of measures to report; reduce the threshold on patients from 60-50%; and only require 90 days of reporting.

- **Eliminate the requirement for physicians to report all-payer data.**

---

• **Only require Yes/No attestations in the EHR Promoting Interoperability Category** and allow physicians to choose from a larger menu of measures applicable to their practice.

• **Enforce EHR vendor interoperability and accountability; require vendors, not physicians, to report on CEHRT functionality and to bear the costs for interoperability updates.**

• **Restore the Small Practice Bonus to the overall MIPS score – do not restrict the bonus to the Quality category.**

• **Reduce the barriers to participation in virtual groups.**

CMA has heard from numerous physicians across the state, in all specialties, from solo practice to large sophisticated medical groups, who made substantial investments in order to participate in the MIPS program. Most of these physicians received high to perfect performance scores for 2017 but have now been told by CMS that they will only receive a 0.2-0.3% bonus for 2017 – if they receive a bonus at all. Physicians are extremely frustrated with the program. We understand that CMS is not responsible for the budget neutrality requirements of MACRA but CMS needs to be aware that the limited return on investment has discouraged many physicians to the point of withdrawing from MIPS and Medicare altogether. Moreover, the Alternative Payment Models are so limited that these physicians cannot participate in the APM track either. Physicians are left without sustainable payment options and few resources to improve the quality of care. We urge HHS and CMS to seriously consider these issues and work with CMA and AMA to address them.

*Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.*

**CMA Recommendation:** ONC should improve its enforcement against vendors who participate in data blocking or violate other certification requirements and help develop systems that allow for automatic extraction of data measures from EHRs.

Difficulty in accessing data hampers industry-wide efforts related to quality improvement, care coordination, patient access to personal health information and reduction in health care costs. Unfortunately, lack of standardization and enforcement at the federal level has allowed for exploitative business practices by EHR vendors. Interoperability is necessary to achieve many of the objectives and measures required to meet meaningful use, such as public health reporting. The inability for a system to be bi-directional has become a barrier as state and federal law require many physicians to report to and check public health registries such as immunization and cancer registries. The lack of interoperability and bi-directional capabilities prohibit physicians from being able to meet federal and state electronic reporting requirements.
Currently, even though the capability for interoperability exists, medical device vendors lack the market imperative to ensure interoperability, largely because providers bear most of the costs of integrating these devices and because there is an absence of an aligned demand to drive change in the technology ecosystem. In the perceived absence of a prominent value proposition, many devices are not integrated with other technologies at all.\textsuperscript{15}

The Office of the National Coordinator of Health Information (ONC) presented a report to Congress on EHR vendor health information blocking practices and discussed how vendors charge prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive. Recently investigators at the University of Michigan conducted a survey of Health Information Exchanges (HIE) nationwide that addressed their experience with information blocking. Fifty percent of respondents reported that EHR vendors routinely engaged in information blocking and 33% reported that EHR vendors occasionally engaged in information blocking. When the survey asked about the form of information blocking used by EHR vendors, 49% reported products with limited interoperability and 47% reported that vendors routinely or often charged high fees for health information exchange unrelated to cost.\textsuperscript{16}

With the rise of data-driven improvements to clinical procedures and processes, it has become increasingly important that quality data be comparable and easy to obtain and use. Payors, both public and private, have varying quality measures which means physicians are required to report multiple quality measures in different ways to different entities. This imposes a significant burden on physician practices as the data must be compiled, a process that often involves manual review of medical charts. Although EHRs could make it easier to obtain the data, there are still manual processes involved that require a significant time investment from the physician practice. Establishing a standardized set of core quality measures and reporting requirements that can be automatically extracted from EHRs would reduce the need for providers and their staff to manually extract and manipulate data measures according to the individual specifications of each entity requiring quality data reporting. This would reduce repetitive procedures; encourage collaboration between providers and data collection entities; and allow for quality data to be compared across providers and plans.

**Public Health Reporting**

*Strategy 1: Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.*

---

\textsuperscript{15} Procuring Interoperability, Pronovost et al (2018) National Academy of Medicine

\textsuperscript{16} There needs to be accountability for the lack of interoperability, Aldinger (2017) Medical Economics available at [http://www.medicaleconomics.com/e-h-r/there-needs-be-accountability-lack-interoperability](http://www.medicaleconomics.com/e-h-r/there-needs-be-accountability-lack-interoperability)
CMA Recommendation: ONC should work with states’ existing regulatory standards to promote interoperability between PDMPs and EHRs.

Integration or interoperability of prescription drug monitoring programs (PDMPs) with health information technology is a new and developing practice with the potential to improve physician workflow. Such integration would automatically query PDMPs by electronic health record (EHR) systems and link patients’ controlled substance prescription history data in PDMP reports with other patient information in the EHR. The goal of integrating PDMP data, like CURES (the California PDMP), with EHRs is to provide a more complete medical record through a single source to support clinical decision-making at the point of care. Integration with health IT makes PDMP data available to prescribers as part of their workflow without the need for multiple user accounts, logons, or user interfaces, thus saving prescribers time and effort.17

The pilots coordinated by the ONC demonstrated the successful automation of queries to PDMPs and integration of PDMP data with EHRs either directly or via health information exchanges. The pilots, although varied in their degree of integrating health IT, showed that as health care providers integrate PDMP data into their day-to-day workflows within health IT, users report the data as easier to access. Prescribers reported increased workflow satisfaction from having each patient’s information as part of the medical record, rather than only for those patients for whom they decided to query the PDMP.18

CMA supports integration of PDMPs with EHRs functionality as it can significantly improve physician workflow. Such integration would automatically query PDMPs by electronic health record (EHR) systems and link patients’ controlled substance prescription history data in PDMP reports with other patient information in the EHR. The goal of integrating PDMP data with EHRs is to provide a more complete medical record through a single source to support clinical decision-making at the point of care.

As of October 1, 2018, California Assembly Bill 40 (2017) allows for interoperability between a HIT system and the CURES database provided the entity that operates the system can certify that it meets certain technical requirements and enter into a MOU with the California Department of Justice. The DOJ was required to develop a programming interface to allow HIT systems to be interoperable with CURES by the Oct. 1 deadline as well.

CMA urges HHS to work with Congress to ensure state PDMPs include dispensing information from federal pharmacies, such as the U.S. Department of Veterans Affairs, U.S.

Department of Defense, Indian Health Services and Opioid Treatment Programs (i.e., methadone clinics).

CMA recommends ensuring that any additional federal standards or requirements to promote the interoperability of PDMPs do not limit or interfere with states that are already moving towards operability and properly protects patient confidentiality. States who have already taken significant steps to integrate their systems should not have to start from scratch or rebuild any interfaces based on new federal requirements.

**Conclusion**

Thank you in advance for your consideration of our comments on ONC’s proposed strategy. California’s physicians look forward to working with you to develop strategies and recommendation that prioritize improving interoperability and using technology to improve patient care. We hope this letter will serve as guidance as this document is finalized and implemented.

Sincerely,

[Signature]

David H. Aizuss, M.D.
President
California Medical Association