TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

June 20, 2023

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Submitted via *Federal Register*

Dear Dr. Tripathi,

On behalf of the Texas Medical Association (TMA) and our more than 57,000 physician and medical student members, we thank you for the opportunity to comment on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule posted to the *Federal Register* on April 18, 2023.

Over the years, TMA and its Committee on Health Information Technology (HIT) have closely followed the certification of electronic health records (EHRs), the Health Information Technology for Economic and Clinical Health (HITECH) Act, the 21st Century Cures Act, and many local and state activities related to physician adoption and use of EHRs and how patient information is shared. It's been 14 years since the enactment of the HITECH Act, which spurred EHR adoption by offering significant incentives and by promoting health care quality, safety, and efficiency.

It's somewhat disappointing that even with all of the technological improvements, EHRs still top the list as a cause of physician burnout and burden. We must do better to enable physicians to efficiently and effectively treat patients with minimal EHR interruption.

TMA offers the following suggestions for consideration by the Office of the National Coordinator for Health Information Technology (ONC).

Low EHR Satisfaction Rates

TMA regularly surveys its members on HIT-specific issues, including EHR satisfaction. TMA's 2023 survey showed a marked reduction in satisfaction rates as depicted in Figure 1. Since 2016, the trend in the percentage of physicians "satisfied" at any level is essentially flat. It also is far lower than other industries would accept.

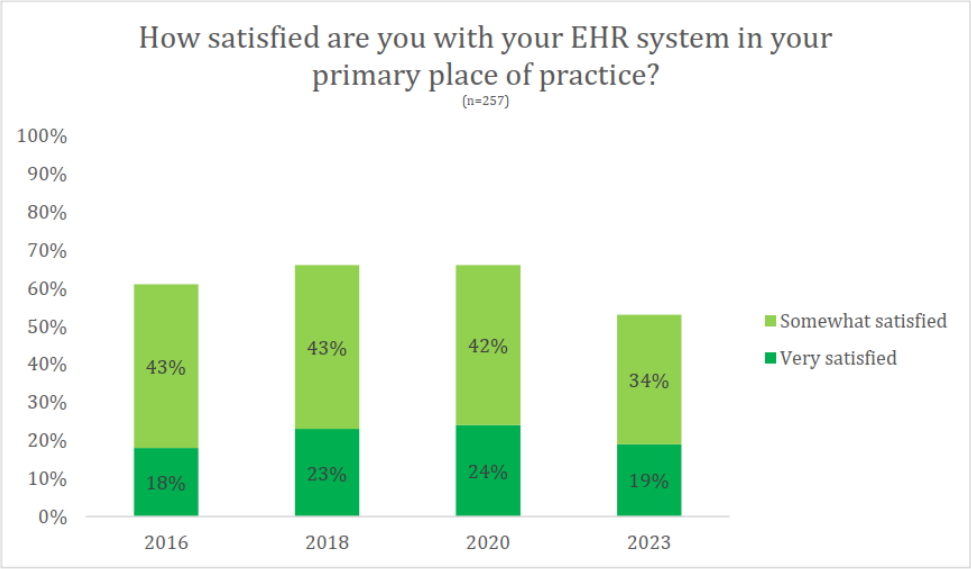

Figure 1

One drag on EHR satisfaction is that ONC and the Centers for Medicare and Medicaid Services (CMS) continue to add insufficiently tested regulatory changes and quality improvement programs. For users, these shortcomings create additional complexities in the health care system that reduce efficiency and satisfaction; for EHR vendors they require the devotion of precious development resources, to the detriment of real usability and efficiency improvements, in order to meet the requirements.

After years of EHR use, it should be the opposite: Physicians should be more proficient and more satisfied. EHR vendors should be enhancing usability through better user interfaces and tools that decrease the user's screen time. Data portability regulations that would allow physicians to switch EHRs rapidly would create competition at the level of the user interface and eliminate vendors with poor satisfaction scores.

TMA urges ONC and EHR vendors to address physician burnout by working on product usability and efficiency rather than adding EHR requirements. This would allow physicians to spend more time on direct patient care, which should increase health care quality and patient safety. The "pajama time" study published in the *Journal of General Internal Medicine* details how the increased clinical effort and excessive time spent in the EHR contributes to physician burnout. TMA implores ONC to use its authority to reverse this trend.

Discharge Consolidated Clinical Document Architecture (C-CDA) Minimum Data-Set Content and Order of Display

Although standardized data elements have been defined in the C-CDA, there is lack of consistency in what elements are shared. Additionally, the data are not prioritized in a way that a physician would logically review the document after a patient's discharge from the hospital.

TMA, as well as other state and national organizations are adopting policy related to the organization of data sent when patients are discharged. TMA recommends ONC, EHR vendors, and health information exchanges adopt the following list as the content and priority of items displayed on a C-CDA when a

patient is discharged from the hospital. The following is the minimum suggested data set of elements and the order in which they should be listed. This recommendation is now published by the Sequoia Project in the Data Usability Workgroup Implementation Guide Version 1.

Discharge C-CDA Minimum Data-Set Content and Display Order:

1. Discharge summary narrative (aka, hospital course)
2. Discharge medications
3. Allergies
4. Admission diagnosis
5. Discharge diagnosis
6. Procedures: Includes interventional radiology, cardiac catheterization, operative procedures
7. Diagnostic imaging: Advanced imaging (e.g., MRI, CT, PET), nuclear imaging, ultrasound, echo, and venous doppler
8. Laboratory: Recommend first and last laboratory result for every test. Rare tests are only done once, so would be included (e.g., anti-nuclear antibodies (ANA) for rheumatoid arthritis)
9. Consultations
10. Assessment and plan: Includes future orders for follow-up with a primary care physicians and diagnostic tests)
11. Problem list

Information Blocking: Ability to Delay Certain Test Results

TMA has heard from numerous physicians about problems arising from the immediate release of test and imaging results that contain negative news about a patient's health. One oncologist told us that his patients have learned about having cancer:

- From a smartphone notification in the middle of a business dinner;
- While reading a bedtime story to a 3-year-old child; and
- During a rush-hour commute.

One patient's wife had to go to the emergency room for treatment of an anxiety attack after reading her husband's CT scan report, only to later learn the scan actually showed the cancer treatment was working. Even when the news is good, some medical test results are too complex to be clear.

Texas is considering legislation that prohibits certain sensitive test results from being disclosed to a patient or patient representative by electronic means by a person or entity that administers or controls the patients' EHR may not disclose the information before the third day after the date the sensitive test results are finalized. This allows time for physicians to discuss the results with their patients in a way that is supported and carefully explained. Similar legislation has been passed in Kentucky and is being considered in other states.

In order to provide national standardization and prevent state-by-state EHR variation, TMA strongly urges ONC to adopt exceptions to "immediate-release" requirements similar to SB 1467 (88th Regular Texas Legislative Session).

Additionally, it is important for certified EHR products to have a standardized way for physicians to hold or delay test results so those results are not automatically pushed to the portal when received by the practice. This is also necessary with the current "Preventing Harm" exception.

In-Basket Message Management

Physicians are overly burdened with in-basket message management, driven for myriad reasons by the influx of messages from patient portals, admit-discharge-transfer data feeds, and other messages. If EHR vendors had the ability to focus on usability and efficiency, EHRs would have out-of-the-box settings allowing care team members to triage messages so physicians can spend more time on patient care and less time reviewing messages that can be handled by others.

TMA urges ONC to make in-basket message management (i.e., efficiency and usability) a priority item for EHR vendor certification criteria.

QHINs and Interoperability

As ONC works with its Recognized Coordinating Entity, The Sequoia Project, to certify qualified health information networks (QHINs), it should consider ways data can be shared from connected EHR vendors without having to build costly interfaces between national networks or local health information exchanges (HIEs). Most EHRs have a connection to either the eHealth Exchange or to CommonWell Health Alliance. Most HIEs also leverage connections to these QHIN candidates.

TMA urges ONC to evaluate the feasibility of leveraging these connections as part of the certification criteria that would allow physicians to exchange patient information without incurring costly interface connections and monthly maintenance fees.

Favorite Lists Destroyed in Upgrades and Outages

Many EHR vendors allow physicians to build "favorites" lists within the EHR. These allow physicians to have a pick list with commonly used orders or medications prescribed. While this functionality is not yet available in all EHRs, those that do have it should build them so they are stable enough to not require being reset or rebuilt after an upgrade or outage. Unfortunately, this is not the case in many EHRs.

TMA recommends ONC determine the feasibility of adding upgrade-stable "favorites" lists to EHR certification criteria.

Advance Care Planning Documents

Patients are encouraged to sign advance care planning directives indicating their desired level of medical treatment during an emergency or at the end of their life. All too frequently, these documents are filed with a physician's practice or other health care setting and not available at the point of care during a medical emergency. There are registries patients can sign up for that retain these documents (some for an annual fee), but that still doesn't solve accessibility if the patient is unable to communicate.

TMA recommends ONC evaluate how this information could be made available at the point of care through a patient query or some other standardized way so a patient's end-of-life wishes are honored.

Read-Only Access to Patient Records

When a physician retires or closes a practice and no longer has access to their EHR, there are not always good options for retaining patient records as required by state record retention laws and regulations. Some physicians and patients solve this problem by printing reams of paper.

TMA recommends ONC consider standardized options for read-only access to patient records so medical record companies that handle medical record requests upon a practice's closing don't have to have EHR-specific knowledge or training. This is a known problem that could be addressed through EHR certification criteria.

In addition to the above general comments, TMA offers the following feedback specific to ONC's proposed regulation.

USCDI v3

ONC proposes adopting USCDI v3 which requires certified EHR vendors to include specific data classes and elements.

TMA Response

TMA appreciates ONC is updating and requiring the standardized sharing of various data classes and elements. It should be noted that for many of the required data elements, there is not a corresponding content standard. Exchanging data elements without a content standard is problematic, and TMA encourages ONC to adopt standards for all required data elements. TMA offers the following suggestions specific to various USCDI v3 data elements:

1. *Care Team Member Name and Location.* Health professionals should have the option to opt in to having their names and identifiers included in the USCDI. There are many situations in which personal harm can come to the professional if their identity is known. In other industries (e.g., a restaurant), the person's first name is on their name tag, not their entire name. When Congress becomes aware that a health professional has been harmed because a patient found their information through the USCDI, ONC will be quick to strike the requirement, but in the meantime, we are all at risk. TMA strongly recommends removal of "Care Team Member Name" and "Care Team Member Identifier" until there are controls over consent to use this information.

Additionally, without standards, each organization will implement the Name, Identifier, Role, and Location differently, which is counterproductive to achieving meaningful interoperability. For example, some will use "Nurse" as the Role, and others will use their internal code for the nurse (e.g., "N" or some number). Without standards, this requirement is meaningless and burdensome without benefit.

2. *Clinical Test Report/Results.* Without "normal" or "abnormal" and/or reference ranges (if appropriate), it is possibly dangerous to send test results. Simply sending the text of a report is often unhelpful. For example, neonatal EKGs frequently have machine readings that are inaccurate. If physicians were to act on these, harm and/or additional expense and worry could occur in some cases. There is nothing in USCDI 3 that specifies the interpretation of a human being is required, which is a serious oversight. Again, the lack of standards for Clinical Test Report/Results and Diagnostic Imaging

Reports allows every organization to do whatever it wants, and this is counterproductive to achieving meaningful interoperability.

3. *Encounter Information.* This section is almost completely lacking in standards. Every organization will do whatever it deems appropriate, and this is counterproductive in terms of achieving meaningful interoperability. TMA strongly recommends only adoption of "Encounter Diagnosis" as it alone has a standard associated with it.

4. *Health Insurance Information.* It is unreasonable to adopt this section when there are no standards for the data elements. Every organization will do whatever it deems best, and this is counterproductive to achieving meaningful interoperability. When standards are adopted, those organizations that implemented fields that don't fit the standard will be forced to rip and replace their work, which is expensive and inefficient. Moreover, ONC will have to specify in a future USCDI version when it is no longer acceptable to have information that does not fit the standard. We strongly recommend implementation of "Health Insurance Information" be deferred until there are defined standards.

5. *Pregnancy Status.* Without standards, all sorts of incompatible data will be entered for this. For an infant, a senior citizen, and a genetic male, for example, there are dozens of ways to say they can't become pregnant. Probably all of these will be used by different organizations, resulting in a lack of meaningful interoperability and future expenses to rip and replace when the time comes to have a standard for this data element. TMA strongly recommends against inclusion of "Pregnancy Status" until there is a defined standard.

6. *Medications Indication and Fill Status*. Lacking standards, these fields will be filled with all sorts of incompatible information. TMA strongly recommends against inclusion of these data elements until standards are established. Fill Status is likely also to be out of date rapidly, and each renewal/refill has its own fill status. The contents of this data element are dangerous if anyone relies upon them.

7. *Demographics: Date of Birth and Death.* Standards for dates exist. Without them, September 29, 09/29/23, 23/09/2023, and many more options are all valid yet not interoperable. TMA recommends inclusion of standards constricting date formats.

8. *Demographics. Previous Name.* Because there are no standards, it is unclear whether this refers to a person's previous first name, middle name, last name, or something else. If there is more than one previous name, there is no guidance on which one should be chosen. TMA strongly recommends against inclusion of "Previous Name" until there is a standard for it.

9. *Demographics. Tribal Affiliation.* Without standards, we are likely to repeat the issues that were encountered with "ethnicity" before there were standards. A plethora of tribal names and spellings will be included in this field, along with "None", "Not Applicable", and a host of other meaningless possibilities. TMA strongly recommends against inclusion of "Tribal Affiliation" until there are standards for it.

10.a. *Problems.* Problems have degrees of importance, which is totally missing in USCDI v3. For example, an ingrown toenail five years ago or a "Well Child Visit" is not the equivalent of Type 1 diabetes or galactosemia. By lacking standards for what a problem is and is not, ONC is sowing seeds of frustration for clinicians as they deal with the unprioritized and far less important issues of a person's health, potentially hiding what's really important.

Below is an example of a real problem list taken from an EHR. It is essentially useless in the management of the patient.

Problem
RESPIRATORY ABNORM NEC
ABDMNAL PAIN UNSPCF SITE
BACKACHE NOS
RESPIRATORY ABNORM NEC
ABDMNAL PAIN UNSPCF SITE
LUMBAGO
OBST CHR BRONC W/O EXAC
HYPERTENSION NOS
CHRONIC PAIN NEC
CHF NOS
DMII WO CMP NT ST UNCNTR
HYPOTHYROIDISM NOS
LONG-TERM USE OF ASPIRIN
HYPOTHYROIDISM NOS
PURE HYPERCHOLESTEROLEM
CHR AIRWAY OBSTRUCT NEC
DMII WO CMP NT ST UNCNTR
ANXIETY STATE NOS
CHF NOS
CHF NOS
CHRONIC OBST ASTHMA NOS
MONONEURITIS NOS
ATRIAL FIBRILLATION
TOBACCO USE DISORDER
CRNRY ATHRSCL NATVE VSSL
LONG-TERM USE OF INSULIN
HYPERTENSION NOS
LONG-TERM USE MEDS NEC
LONG-TERM USE MEDS NEC
TOBACCO USE DISORDER
INJECT/INFUSE NEC
INJECT/INFUSE NEC
THER/PROPH/DIAG INJ, IV PUSH
THER/PROPH/DIAG INJ, IV PUSH
TX/PRO/DX INJ NEW DRUG ADDON

10.b. *Problems - Date of Diagnosis and Resolution.* Without standards, September 29, 09/29/23, 23/09/2023, and many more options are all valid – and not interoperable. We recommend inclusion of standards constricting date formats.

11. *Vital Signs.* Without dates and times, these are essentially meaningless and potentially dangerous. It is unclear whether these are the last vitals, the lowest values, the highest values, or something else. If there is more than one measurement over time, e.g., head circumference, there is no guidance on how the historical values are to be included. TMA strongly recommends standards so that there is not confusion

In summary, TMA recommends ONC adopt only the USCDI v3 data elements that have a corresponding standard rather than the full suite of data classes and elements. ONC can then work on adopting

standards for the remaining data elements for future implementations. To do otherwise is to value quantity over quality and to value a Tower of Babel over true meaningful interoperability.

Additionally, there should be real-world testing indicating that all data elements have bidirectional semantic interoperability. There should be evidence that what is required is useful for patient care and does not increase cognitive burden and physician workload. The latter is where vendors should be spending their time, not on adding new data elements without standards.

Electronic Case Reporting

ONC proposes adoption of three standards-based requirements for certified Health IT Modules. These requirements would enable users to 1) consume and process trigger codes that identify a reportable encounter based on a reportable condition match; 2) create a case report; 3) receive, consume, and process a case report response; and 4) transmit a case report.

TMA Response

TMA appreciates ONC's proposal to standardize electronic case reporting that is responsive to state and local requirements. TMA asks that as a condition of certification, vendors have a mechanism that allows users to review data before authorizing submission. As the systems evolve, there may be a need to ensure correct data is appropriately submitted. It's easier to verify than to claw back erroneous submissions.

Decision Support Interventions and Predictive Models

ONC recognizes that expanding use of predictive models and artificial intelligence in health care are demonstrating value in many circumstances. ONC also understands the potential for a variety of risk types that can lead to unintended consequences and adverse events on patients. Therefore, ONC is proposing various requirements for health IT products related to standards, configuration, and source attribution that will lead to greater transparency of how predictive modeling and artificial intelligence is used in certified products.

TMA Response

TMA applauds ONC for its recognition of the potential risks of clinical decision support tools driven by predictive modeling, machine learning, and artificial intelligence. TMA agrees in principle with ONC's proposals designed to mitigate these potential risks, but requests that ONC ensure the information provided in the 14 new source attributes for predictive decision support interventions (DSI) are useful and understandable. The inherent risks of DSI use should be shared among developers, distributors, and users, with each entity owning responsibility for its respective role in the development, dissemination, and use of products used in clinical care.

As DSI becomes more integrated in EHRs, it is important that physicians have a way to report when the information provided to them is amiss. TMA recommends ONC support a centralized, national repository of HIT-related issues that have potential for patient harm. Health IT was initially promoted as a way to reduce errors and increase patient safety; it actually has introduced new types of errors that could be exacerbated with DSI. Physicians need to be able to report glitches and other problems quickly in a workflow-friendly way. Reporting tools should be developed within EHRs and other HIT products that capture standardized background system-level information with a single click and send it to an

appropriate reporting body. Federal oversight is needed to monitor and manage EHR patient safety, similar to how the National Transportation Safety Board manages transportation safety. ONC could explore working with the private sector to develop a national repository for reporting.

TMA's recently adopted policy, "Augmented Intelligence in Health Care" supports ONC's proposals and provides additional policy guidance for ONC's consideration:

> **Augmented Intelligence in Health Care**
>
> The Texas Medical Association supports the use of augmented intelligence (AI) when used appropriately to support physician decision-making, enhance patient care, and improve public health. Augmented intelligence should also be used in ways that reduce physician burden and increase professional satisfaction. Sufficient safeguards should be in place to assign appropriate liability inherent in augmented intelligence to the software developers and not to those with no control over the software content and integrity, such as physicians and other users.
>
> The Texas Medical Association adopts the following principles for augmented intelligence in health care:
>
> 1. Augmented intelligence should be the preferred health care term over artificial intelligence as it should be used to augment care by providing information for consideration. Augmented intelligence, whether assistive or fully autonomous, is intended to co-exist with human decision-making and should not be used to replace physician reasoning and knowledge.
> 2. Physicians should not be mandated to use augmented intelligence.
> 3. Augmented intelligence must not replace or diminish the patient-physician relationship.
> 4. Algorithms developed to augment user intelligence must be designed for the benefit, safety, and privacy of the patient.
> 5. Sellers and distributors of augmented intelligence should disclose that it has met all legal and regulatory compliance with regulations such as, but not limited to, those of HIPAA, the U.S. Department of Health and Human Services, and the U.S. Food and Drug Administration.
> 6. Use of augmented intelligence, machine learning, and clinical decision support has inherent known risks. These risks should be recognized and shared among developers, distributors, and users with each entity owning responsibility for its respective role in the development, dissemination, and use of products used in clinical care.
> 7. Users should have clear guidelines for how and where to report any identified anomalies. Additionally, as with all technology, there should be a national database for reporting errors that holds developers accountable for correcting identified issues.
> 8. Before using augmented intelligence, physicians and all users should receive adequate training and have educational materials available for reference, especially in instances where the technology is not intuitive and there are periods of nonuse.

9. Physicians should inquire about whether the AI used is a "continuously learning system" versus a "locked system." A locked system is more appropriate for clinical care, although a hybrid system may be appropriate as long as the clinical output is based on locked training sets.
10. Algorithms and other information used to derive the information presented as augmented intelligence to physicians and other clinicians should:
    a. Be developed transparently in a way that is accessible, explainable, and understandable to clinicians and patients and details the benefits and limitations of the clinical decision support, and/or augmented intelligence;
    b. Have reproducible and explainable outputs;
    c. Function in a way that promotes health equities while eliminating potential biases that exacerbate health disparities;
    d. Use best practices for user-centered design that allows for efficient and satisfactory use of the technology;
    e. Safeguard patient information by employing privacy and security standards that comply with HIPAA and state privacy regulations; and
    f. Have a feedback loop that allows users who identify potential safety hazards to easily report problems and malfunctions as well as opportunities to report methods for improvements.
11. Medical students need to learn about the opportunities and limitations of augmented intelligence as they are prepared for future medical practice.
12. Recognizing the rapid pace of change in augmented intelligence, it is important to continually assess and update TMA's principles at regular intervals (JR 8 2022).

Real World Testing – Inherited Certified Status

ONC proposes that in their real-world testing results report, all developers be required to include the most recent version of health IT modules that are updated using "Inherited Certified Status."

TMA Comment

TMA appreciates that ONC recognizes the gap created with the Inherited Certified Status, which could result in the inadvertent exclusion of existing certified vendors from the real-world testing and reporting requirements. Real-world testing is a critical component of verifying that the health IT works in the production environment as intended in the testing environment.

TMA appreciates the opportunity to provide feedback on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. Any questions may be directed to Shannon Vogel, associate vice president of health information technology, by emailing shannon.vogel@texmed.org or calling (512) 370-1411.

Sincerely,

Rick W. Snyder II, MD
President
Texas Medical Association