

Monday, June 17, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW
Washington, DC 20201

Dear Dr. Rucker,

I am pleased to submit our comments on ONC's TEFCA Draft 2 proposal. I hope you find them informative and constructive.

BACKGROUND

If you recall our brief conversation at ONC's Annual meeting in November/December 2017, I whole-heartedly support ONC's original objectives as stated in President George W Bush's 2004 Executive Order (see Exhibit1), but strongly disagree with the system ONC has mandated since then culminating in TEFCA, Draft 2 that is intended to achieve national interoperability of patient medical records.

When you asked at that meeting for suggestions, I suggested that ONC stop writing new rules and mandates, such as TEFCA, and waive the vestiges of Meaningful Use that are still in effect because they don't and won't work. These actions would free up IT and other personnel to consider and evaluate innovative solutions that do work. And I urged you to have ONC nurture other approaches — such as the patient-focused approach our company has taken — that achieves interoperability easily, immediately and inexpensively today.

Like your predecessors, you responded that ONC was simply carrying out what Congress has ordered. (I was disappointed to read their joint letter supporting TEFCA Draft 2. Surprisingly, they haven't changed their position even though they know that linking silos doesn't work!)

Bottom line: While most of our physicians and hospitals use electronic medical records, which is a major accomplishment, we're no closer to achieving "Total Interoperability" today — where a patient's COMPLETE medical record from ALL his or her providers is available anytime, anywhere he or she requires care — than we were in 2004!

When one asks "why" after we've spent 15 years and tens of billions of dollars, the answer is always "it's the other guy's fault!" Physicians blame hospital administrators and EMR system vendors. They, in turn, blame the "government." The "government," namely ONC, HHS, CMS, blames Congress. And Congress says they are forced to micromanage the solution because providers and vendors aren't pressing to achieve interoperability on their own! And so it goes, round and round — spending more and more time and money with little-to-no progress to show for it!

There is another group that we believe is really responsible for our lack of interoperability. It consists of all those thinkers and policy wonks who have sold ONC, CMS, HHS, and Congress a bill of goods that linking provider silos via health information exchanges (HIEs — now referred to in the TEFCA Draft as HINs and QHINs) is the way to achieve interoperability. This was the "vision" at the outset, and it is still being pursued today even though it doesn't work!

In our opinion, it is this rigid adherence to a flawed approach that has caused us to fail, and will continue to do so. And the consequences have been severe. Over the years, millions have been made sicker rather than better, more than a million have died and we've wasted several hundred \$billion!

We weren't present at your "listening" sessions but no one seems to have "heard" the complaints and serious consequences, both direct and indirect, that have emerged since providers were forced to adopt EMR systems.

The direct consequence is that we aren't even close to having a national network that enables a doctor to access his or her patient's complete record when they need it — which is the only measure that counts! (Claims by EMR vendors that they exchange millions of records daily completely miss the point and are totally irrelevant.)

The unintended consequences are even more troubling! They have compounded the problem and undermined the entire effort. They include:

- 1) the unchecked emergence of an oligopoly of EMR system vendors who dominate the market. They decide what kinds of systems are available, set very high prices for their

- systems and require their customers to pay excessive annual support fees. (In a free market, vendors would not get away with these practices and charges.)
- 2) the establishment of overly complex record systems which are disliked — even hated — by most providers, seriously detract from provider–patient interaction, cause widespread physician “burnout” and patient dissatisfaction, and make it difficult and extremely expensive for providers to change EMR systems.
 - 3) the financial strains caused by overly costly EMR systems that have forced many providers to sell their practices to hospitals, many hospitals to merge and many to fail.
 - 4) the need for elaborate costly supporting systems that attempt to overcome shortcomings of HIEs/HINs, such as patient registries to ensure proper patient identification and record matching.
 - 5) the inability of already overwhelmed IT personnel to consider, test and evaluate alternative approaches which may better meet care providers’ and patients’ needs and provide better care at lower cost. The adoption of TEFCA — no matter how noble its intentions — will make matters dramatically worse. It will tie up IT personnel for several years as they implement the required changes, and ensure that innovative solutions that provide Total Interoperability do not see the light of day for years to come!
 - 6) the wasting of not only billions of dollars and untold man–years, and causing enormous pain, suffering and even death to hundreds of thousands but also wasting the talents of the thousands of dedicated personnel who, if free to do so, could develop systems that actually work.

RECOMMENDATIONS

We respectfully propose the following action steps to put us on a new path that will save time, lives, and treasure, quickly achieve Total Interoperability, actually improve the quality of care and reduce its excessive cost.

- 1) Establish “Total Interoperability” as the primary goal of patient record sharing. Providers should be able to immediately access their patients’ COMPLETE lifetime medical record from ALL their providers at the point of care, anytime, anywhere.
- 2) STOP forcing providers to adopt EMR systems that standardize the way records are kept. That’s like to trying to “cut the man to fit the cloth!” Not all providers like, want or need to keep records the same way.
- 3) STOP all efforts to link provider silos via HIEs/HINs. This includes dropping TEFCA and discontinuing any lingering Meaningful Use requirements. (It also may require the House of

Representatives to revoke or abandon the instructions contained in the 21st Century Cures act that call for TEFCA.)

- 4) Aggressively enforce the anti-blocking rules and fines spelled out in the 21st Century Cures Act.
- 5) REQUIRE that patients control their records and always carry them with them so they are immediately available when needed (just as we do today with drivers' licenses).
- 6) IDENTIFY and, as soon as possible, TEST at least two or three alternate programs or applications that promise to provide "Total Interoperability," then ADOPT one or two that work and can be implemented quickly.

To be considered, a system should meet the following nine criteria:

- 1) focus on how records are MANAGED rather than on how they are kept.
- 2) give the PATIENT CONTROL of his or her records so they can "move" with the patient and always be available when needed.
- 3) ensure that any record in ANY FORMAT (including paper notes and scanned documents) can be electronically sorted, searched, corrected if necessary and read by providers and patients.
- 4) contain COMPLETE notes rather than summaries.
- 5) permit the EASY, SECURE and FREE exchange of records among providers, patients, researchers and others designated and authorized by the patient.
- 6) ensure that records are SECURE, ACCURATELY MATCHED to the correct patient, and accessible even during power and internet outages and natural disasters.
- 7) BLEND into provider workflow, SAVE providers time and enable them to avoid medical errors and unnecessary visits, tests, procedures.
- 8) require NO special training, be EASY TO USE and AFFORDABLE by everyone, and financially self-sustaining.
- 9) be FLEXIBLE enough to accommodate changes that may be introduced in the future as provider systems are improved.

CASE STUDY

As evidence that such a system can work and provide the desired "Total Interoperability," allow us to describe the innovative MedKaz® patient-focused personal health record and communication system our company has developed. (Other innovators may ALSO have approaches worth considering.)

MedKaz[®] Example



MedKaz reimagines how patient records can be shared and used. Its common sense approach to Total Interoperability and record-sharing leapfrogs over the problems the linking-silos approach creates but can't solve.

There are two fundamental differences between the two approaches. First, MedKaz focuses on *managing* disparate patient records; linking-silos tries to standardize how records are *kept*. Second, MedKaz satisfies the nine criteria previously cited; linking-silos doesn't come close.

The most important fact to know about MedKaz is that it achieves Total Interoperability *today*, making the many benefits we all expect from Total Interoperability available *today!*

MedKaz enables providers to access a patient's lifetime health record in one place and actually deliver better care at much lower cost. It empowers patients to participate in their care management and share their records with whomever they wish. And it provides the foundation for major improvements in the way care is delivered, organized and paid for.

MedKaz is patient-focused. It assembles a patient's Lifetime Health Record, and the application to manage it, on a MedKaz minidrive. The patient carries his or her MedKaz on a keychain or wears it, and gives it to any provider they see anytime they need care — at home or away, in an emergency or routine visit. It is updated after each encounter.

- It is charting-system agnostic and employs what is arguably the most widely used and universally accepted standards for managing disparate documents. It turns ANY document (including paper charts) into a pdf document, makes it SEARCHABLE, and displays it in a familiar browser.
- Each MedKaz can store and manage the records of multiple family members, including pets.
- Providers and patients can electronically SEARCH its contents and CORRECT mistakes in records if there are any. Records open to the first page containing the search term, which is highlighted for instant access.
- Records can be shared as both pdf documents and structured data.
- Patients can share their records with care providers; also with others such as family members, care givers and researchers. Soon, patients in one city will be able to share their records with family and friends in other cities. (This will enable elderly parents in one city to share their records with their adult children in other cities.)

- o MedKaz is affordable by 57± million Americans who do not have smartphones but are disproportionately heavy users of healthcare. They include almost 30 million seniors 65+ and older, and individuals with incomes below \$50K/year.
- o It requires no special training, meets everyone's needs, and benefits everyone financially. If you can log on to a computer, perform a search and read a document in a browser, you can use MedKaz!

Care providers use it to quickly get up to speed with their patient's health issues (which saves them time), and to access their patient's Lifetime Health Record so they can coordinate their care and avoid costly medical errors and redundant or unnecessary visits, tests and procedures. (Exhibit 2 graphically shows how MedKaz blends seamlessly into a provider's workflow. Exhibit 3 compares MedKaz to other systems.)

With MedKaz, patients receive better care while saving deductibles, copays and time away from work. Employers, insurers and government enjoy increased employee/insured productivity and greatly reduced health insurance costs. Providers can deliver better care and, thanks to the unique MedKaz business model, enjoy new income.

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Thank you for considering our comments. We'd be pleased to discuss them with you at your



Exhibit 1

Executive Order 13335—Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator *

April 27, 2004

Sec. 2. Policy. In fulfilling its responsibilities, the work of the National Coordinator shall be consistent with a vision of developing a nationwide interoperable health information technology infrastructure that:

- (a) Ensures that appropriate information to guide medical decisions is available at the time and place of care;
- (b) Improves health care quality, reduces medical errors, and advances the delivery of appropriate, evidence-based medical care;
- (c) Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information;
- (d) Promotes a more effective marketplace, greater competition, and increased choice through the wider availability of accurate information on health care costs, quality, and outcomes;
- (e) Improves the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information; and
- (f) Ensures that patients' individually identifiable health information is secure and protected.

*** Excerpted from the Federal Register**

Exhibit 2

How to use medkaz[®]

Care Provider instruction sheet by Health Record Corporation (HRC), creator of the MedKaz.

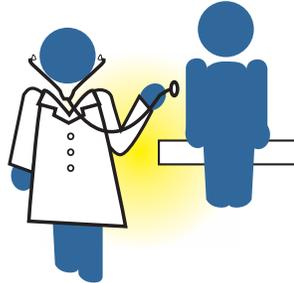


1 Plug in and open MedKaz

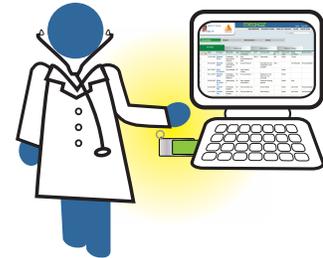


2 Read Time-Saving Documents: Referral Request, Complaint Report, Health Summary

3 Treat patient as usual



4 Sort/Search/Read records as needed



5 Complete Progress Notes and Encounter Summary



6 Fax/ Mail/ Upload* copies of all documentation to MedKaz



Exhibit 3

How MedKaz Compares

Features	<u>MedKaz</u> [®]	Apple Health	HIE Networks	Paper
• Patient owns, controls; moves with patient	✓	✓		
• Instantly available anytime, anywhere	✓	✓		
• Contains patient's complete record from all providers past and present, in all cities, states	✓			
• Complete notes, not summaries, accessible with two or three clicks	✓		✓	
• Providers and patients can electronically sort, search, read, manage all records, including paper; patients can correct mistakes	✓			
• Patient can automatically share records with doctors, parents, children, care givers, researchers, others	✓			
• Easy to use, no special training required	✓	✓		✓
• Updated for patient	✓	✓		
• Secure, password controlled to two levels	✓			
• Patient can lock individual records	✓			
• Records available during power, Internet outages, natural disasters	✓	✓		✓
• Reduces cost of care for everyone: patients, employers, payers, government	✓			
• Patients save money; providers enjoy new income; employers, insurers, government save money	✓			
• Affordable by everyone; financially self-sustaining	✓			✓