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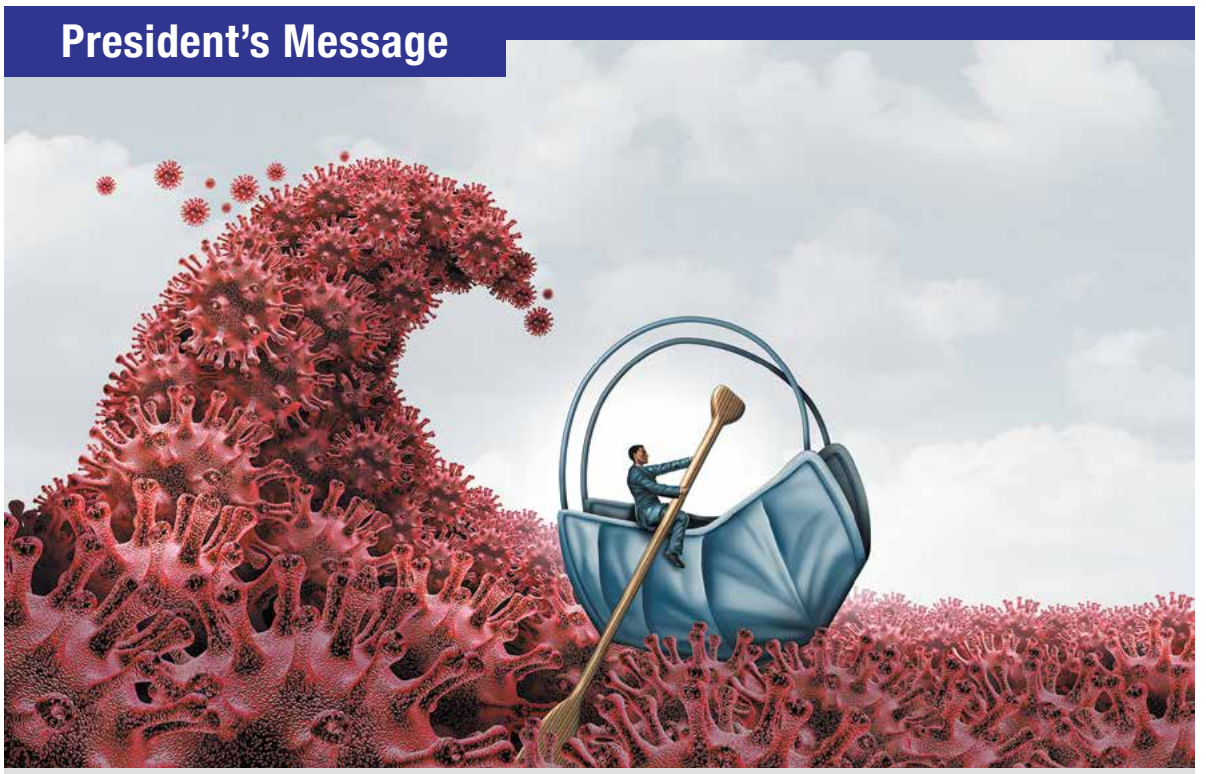
President's Message



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Getting through it together

"But I know, somehow, that only when it is dark enough can you see the stars."

— Martin Luther King Jr.

By Brendan G. Carney

When I assumed the presidency of MATA on July 1, 2020, I knew this year was going to be different. The COVID pandemic did not allow the traditional in-person passing of the gavel that we see in typical years. By that time, working from home was the norm and "Zoom" had become a household word. Unfortunately, it was just the beginning of the changes we have weathered over the past months.

In that first week of July, we learned that MATA Past President Edwin "Ed" Wallace had passed away suddenly, years into a Parkinson's diagnosis that never seemed to slow him down. Ed inspired many of us, and I was lucky to have known him personally for much of my life.

Ed was part of the fabric of MATA, and the organization will never be the same without him. As trial lawyers, we know that tragedy is part of life, but when it hits so close to home, our professional objectivity is not really helpful. (See in memoriam statement in this issue.)

The following months brought even more heartbreak to our legal community and the nation at large. We were shocked to learn of the untimely death of beloved SJC Chief Justice Ralph Gants, closely followed by the

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EDITOR'S NOTE

Turn and face the strange changes

By Jonathan A. Karon

My last column was written in April. At that time, courts were handling emergency business only, jury trials were on hold, and we were learning how to work remotely. We've come a long way since then, but our practices are still quite different. Below is a list of some of the most significant changes and my thoughts on them.

Remote depositions

This may be the biggest. Once the SJC allowed Zoom depositions as of right, we were able to start moving our cases forward again. In practice, I've found that Zoom depositions work remarkably well and that the technical obstacles are minimal.

The biggest difference is the handling of exhibits. Previously, when preparing for a deposition, I'd complete my outline and then assemble the exhibits. Now I have to decide on exhibits first, so that they can be forwarded to the court reporter and opposing counsel.

Although you can have the court reporter mark and share the exhibits, I prefer to do this myself. I'm getting much better with screen sharing, although it's still an adventure. By the way, it is possible to have a witness mark a document while it's being shared on Zoom.

There are some other logistical issues. You have to make it clear that the witness is not allowed to communicate with counsel during

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Animations in personal injury cases

By Doug Sheff

Often times the difference between a good lawyer and a great one is his or her ability to use demonstrative evidence in a frequent and effective manner. Whether at trial or mediation, a constant and coherent presentation of visual aids can make a huge difference in both presentation and results.

One example of demonstrative evidence is an animation. Actually, animations may be admitted as evidence or utilized simply as a chalk (see *Lally v. Volkswagen*, 45 Mass. App. Ct. 317 (1998); John W. Strong et al., McCormick on Evidence §214, at 21 (West 5th ed. 1999 & Supp. 2003). In either instance, they can advance your case in many ways.

ALL STAR TIPS

Over the past several years, the attention span of jurors has grown increasingly shorter. Technology has created an expectation to receive information in a quick, concise and easy-to-understand manner. In addition, the old saying "seeing is believing" applies to jurors more now than ever before. For these reasons, we now see animations viewed favorably in focus groups as compared to similar groups in the past.

> For today's increasingly inattentive jurors, an animation can mean the difference between victory and defeat.

Properly done, an animation can summarize years of investigation, discovery, witness testimony and expert analysis in a matter of seconds. It can distill complex and sometimes technical information into a simple, easy-to-digest and persuasive expression of an event.

In order to make your animation relevant or even admissible,

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Update on HITECH medical records requests

By Kevin J. Powers

This article updates an earlier discussion from the March 2020 issue of the MATA Journal regarding the HITECH Act, 42 U.S.C. §17935(e), and associated regulations at 45 C.F.R. §164.524.

In January, the federal District Court for the District of Columbia struck down a Department of Health and Human Services (DHHS) rule that had previously applied the HITECH patient rate not only to medical records requests in which the records are to be sent directly to the client/patient, but also to medical records requests in which the records are to be sent to "an entity or person designated" by the patient. See generally *Ciox Health, LLC v. Azar*, 435 F. Supp. 3d 30 (D.D.C. 2020).

Although Judge Mehta grounded the decision in *Ciox* on procedural point — the failure of DHHS to provide notice and opportunity for comment on the rule by interested persons pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §553 — the result of the decision was a very substantive change in how attorneys facilitate HITECH requests for clients.

After *Ciox*, counsel was faced with two options: either draft the HITECH request letter to direct that the provider send the records directly to the client/patient or prepare the client/patient for a big bill reflecting the fact that records shipped to counsel no longer fell within the low HITECH patient rate.

All hope is not lost, however. This article will discuss new DHHS regulations that may provide a new enforcement mechanism for HITECH requests, but that may also create opportunities for medical records contractors to continue to erect roadblocks on the way between patients and their medical records.

45 C.F.R. §171.302. On June 30, 2020, DHHS regulations implementing the 21st Century Cures Act, 130 Stat. 1176 (2016), became effective. See, e.g., 45 C.F.R. §171.302 (2020).

Most relevant to HITECH are the regulations implementing "information blocking" prohibitions and penalties codified at 42 U.S.C. §§300jj-52 (2016). See 45 C.F.R. §171.100 (2020). "Information blocking means a practice that ... [e]xcept as required by law or covered by an exception ..., is likely to interfere with access, exchange, or use of electronic health information." 45 C.F.R. §171.103(a) (2020) (defining information blocking and delineating knowledge requirements for entities conducting information blocking).

The key regulation answers the question "when will an actor's practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking?" 45 C.F.R. §171.302 (2020).

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An "actor" is "a health care provider, health IT developer of certified health IT, health information network or health information exchange." 45 C.F.R. §171.102 (2020). "An actor's practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using electronic health information will not be considered information blocking when the practice ... does not include any of the excluded fees in paragraph (b) of this section ... ." 45 C.F.R. §171.302 (2020).

Paragraph (b) of 45 C.F.R. §171.302 is the connective tissue that links the 21st Century Cures Act to HITECH. Among the "excluded fees" to which the 45 C.F.R. §171.302 fees exception does not apply — that is, among the "excluded fees" that DHHS may consider "information blocking" — is "[a] fee based in any part on the electronic access of an individuals' [electronic health information (EHI)] by the individual, their personal representative, or another person or entity designated by the individual." 45 C.F.R. §171.302(b)(2) (2020).

DHHS contemplated HITECH. DHHS intended 45 C.F.R. §171.302(b)(2) to encompass HITECH requests, stating explicitly that "[t]he [fees] exception [in the first clause of 45 C.F.R. §171.302] does not apply to fees prohibited by 45 C.F.R. §164.524(c)(4)," which regulation implements HITECH. 21st Century Cures Act Regulations, 85 Fed. Reg. 25,885 (2020).

DHHS on scope of HITECH fees. Judge Mehta in *Ciox* held that the 2016 DHHS Guidance, which clarified that providers may charge a fee for "labor for copying" but may not charge any fee for the cost of labor associated with "locating the data," remains in force. *Ciox*, 435 F. Supp. 3d at 67-68.

DHHS stands by this limitation: "[t]he fee may include only the cost of: (1) [l]abor for copying ...; (2) supplies for creating the paper copy or electronic media (e.g., CD or USB drive); (3) postage ...; and (4) preparation of an explanation or summary." 21st Century Cures Act Regulations, 85 Fed. Reg. 25,885 (2020).

Focus on automated internet "portal" access. The DHHS Federal Register notes distinguishing between search costs and copying costs further suggest what the regulations now make clear: that the HITECH-related regulations implementing the 21st Century Cures Act are truly concerned not with medical records provided on USB sticks, CDs or DVDs, but instead with medical records provided through internet portals.

"Electronic access means an internet-based method that makes electronic health information available at the time the electronic health information is requested and where no manual effort is required to fulfill the request." 45 C.F.R. §171.302(d) (2020). Thus, "a health care provider that charges individuals a fee ... to receive access to their EHI *via the health care provider's patient portal or another internet-based method*, would not be able to benefit from [the fees] exception [in the first clause of 45 C.F.R. §171.302]." 21st Century Cures Act Regulations, 85 Fed. Reg. 25,886 (2020) (emphasis added).

On the other hand, portals present their own problems. The "patient portals" commonly used by clients/patients to view their ongoing medical information on-the-fly — perhaps the "health care provider's patient portal" referenced in the DHHS Federal Register notes — often offer only stripped-down versions of patient charts and of office or consultation notes.

"Patient portal" information is therefore often very different from what a HITECH request should yield, i.e., the actual and complete patient chart.

What, then, of "requestor portals" specifically provided by medical records contractors to records requestors — perhaps the "another internet-based method" referenced in the DHHS Federal Register notes?

Medical records contractors often preface access to "requestor portals" with draconian click-through agreements, which attempt to do via contract what the medical records contractors are not allowed to do via statute and regulation: charge ludicrously high medical records access fees. Such language often includes a stipulation that the user assents to paying any charges applied to his or her portal account by the medical records contractor. Consequently, it may be that the shift from USB sticks, CDs and DVDs to internet portals will simply mean that counsel will spend less time arguing with medical records contractors about non-compliant invoices for boxes of paper and spend more time arguing with medical records contractors about non-compliant portal access invoices.

All of this doubtless amounts to enough ambiguity to create disputes between requestors and medical records contractors for years to come.

Does counsel receive the HITECH rate? Arguably ... On the one hand, the regulations exclude from the fees exception a fee for electronic access "by the individual, their personal representative, *or another person or entity designated* by the individual." 45 C.F.R. §171.302(b)(2) (2020) (emphasis added).

On the other hand, the DHHS Federal Register notes suggest a different sort of designee, referring to "sharing it with an entity designated by the individual (e.g., allowing individuals to donate/share EHI with a biomedical research program of the individual's choice)." 21st Century Cures Act Regulations, 85 Fed. Reg. 25,887 (2020).

At another point, the DHHS Federal Register notes suggest an app rather than an attorney: "[t]hese other individuals or entities (e.g., a third-party app) receive access to EHI at the direction of the individual and individuals control whether the third-party receives access to the individual's EHI." *Id.* at 25,886.

The regulations also invoke ambiguous language in excluding from the definition of EHI "[i] nformation compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding." 45 C.F.R. §171.102 (2020).

The phrase arguably would not refer to information "provided" as maintained in the provider's electronic system, rather than "compiled" specifically for purposes of the medical records request. The phrase arguably would not refer to information compiled during the claim stage of a case, prior to filing suit. On the other hand, counsel should anticipate that even this sort of logic and good sense will be unlikely to stand in the way of medical records contractors offering even implausible arguments against compliance with HITECH.

Effective date is not compliance date. The DHHS regulations became effective on June 30, 2020, but compliance is required by Nov. 2, 2020. 45 C.F.R. §171.101(b) (2020).

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Update on HITECH medical records requests

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DHHS on standard of review applicable to information blocking. DHHS is clearly fed up with the gamesmanship of medical records contractors; little else could explain its decision to "emphasize that an actor's practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual's EHI would be inherently suspect under an information blocking review." 21st Century Cures Act Regulations, 85 Fed. Reg. 25,792 (2020).

"Patients have already effectively paid for their health information, either directly or through their employers, health plans, and other entities that negotiate and purchase health care items and services on their behalf." *Id.* at 25,886.

All of this suggests that challenging information blocking by medical records contractors can be a fruitful exercise for those attorneys and clients/patients willing to undertake the effort.

DHHS on delay tactics by medical records contractors. DHHS alludes to "commenters" urging delay in implementation of the new regulations well beyond the current Nov. 2, 2020, enforcement date: "commenters recommended that [the Office of the Inspector General (OIG)] not take any enforcement action for a period of 18 months or two years after the effective date of the final rule." 21st Century Cures Act Regulations, 85 Fed. Reg. 25,792 (2020).

Indeed, "[s]ome commenters recommended a period of enforcement discretion of no less than five years during which OIG would require corrective action plans instead of imposing penalties for information blocking. One commenter also recommended that [DHHS] 'grandfather' any economic arrangements that exist two years from the date of the final rule." *Id.*

DHHS did not identify the "commenters" in question, but it is difficult to avoid speculating that those "commenters" were probably some of the same medical records contractors that have spent a decade or longer deftly attempting to avoid compliance with HITECH.

In any event, DHHS did not yield — much: "[t]aking these comments into consideration, we have delayed the compliance date of the information blocking section of this rule (45 CFR part 171). The compliance date for the information blocking section ... will be six months after the publication date of this final rule." *Id.* And so it is: Nov. 2, 2020. 45 C.F.R. §171.101(b) (2020).

One other delay is worth bearing in mind. "Until May 2, 2022, electronic health information for purposes of [information blocking] is limited to the electronic health information identified by the data elements represented in the [United States Core Data for Interoperability (USCDI)] standard adopted in [45 C.F.R.] §170.213." 45 C.F.R. §171.103(b) (2020). The USCDI Version 1 standard is beyond the scope of this article, but is available at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi (last accessed Oct. 7, 2020).

But do not expect certified medical records. Refusing to provide certified medical records to counsel is one way that medical records contractors have placed pressure on counsel to submit an additional, non-HITECH request. It is unlikely that medical providers will begin gladly certifying medical records directed to a client/patient. See the March 2020 MATA Journal article for a discussion of this issue.

Best practices after Nov. 2, 2020. Truly cautious counsel, perhaps doubtful that counsel will qualify as "another person or entity designated by the" client/patient, might still do well to draft HITECH letters so as to direct that the provider ship the records directly to the client/patient.

If counsel insists on listing himself or herself as the recipient of the medical records, then counsel should draft HITECH letters to request access to medical records via an internet portal, in order to avoid an active "copying" step through which a medical records contractor might legitimize HITECH-noncompliant fees.

As under pre-*Ciox* practice, HITECH letters should bear the client's letterhead and signature. HITECH letters should demand that the provider advise as to any records available only as paper copies, and as to the cost of copying any records, prior to the provider sending such records.

All HITECH letters should invoke the HITECH Act and its regulations, while a HITECH letter requesting that the provider send records directly to counsel should also invoke the regulations implementing the information blocking restrictions of the 21st Century Cures Act.

If the provider and the contractor refuse outright to comply with HITECH, or refuse to adjust an invoice to either the $6.50 flat rate or a fee truly reflective of the actual cost of making a digital copy of digital records, then counsel should file a complaint with the DHHS Office of Civil Rights. Note that the more formal procedure for obtaining review of a HITECH denial is set forth in 45 C.F.R. § 164.524(d)(4).

Above all, prepare for a fight. Years ago, a very large and very profitable medical records contractor industry was built on charging what could easily be described as unreasonable fees. The big medical records contractors will not give up without a fight, and their resistance will take every available form.

Kevin J. Powers has been active in the Massachusetts appellate bar since 2006, a member of MATA's Amicus Committee since 2017, interim chair of the Amicus Committee from 2018 to 2019, and current vice chair of the Amicus Committee. His reported decisions include Meyer v. Veolia Energy N. Am., 482 Mass. 208 (2019), and he has co-written or edited several of MATA's recent amicus filings. He can be reached at kpowers@kevinpowerslaw.com.