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INSIDE:

Physicians and Meaningful Use of Certified Electronic Health Records: Kicking the Can Down the Road

By: McKenzie A. Livingston, Esq. [1]

The American Recovery and Reinvestment Act of 2009 included the enactment of the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"). The HITECH Act encourages healthcare providers to adopt electronic health records ("EHR") by 2015, which meet certain requirements established by the Secretary of the United States Department of Health and Human Services ("HHS").

In order to encourage the move from paper records to EHRs, the HITECH Act appropriated approximately $25 billion for the HHS to promote and expand the adoption and use of EHRs, including incentive payments for healthcare providers who adopt and utilize EHRs. The HHS created the Medicare and Medicaid Electronic Health Record Technology Incentive Program (the "EHR Incentive Program"), which provides payments to those healthcare providers who adopt certified EHR technology and demonstrate the meaningful use of that technology on a yearly basis.[2] The EHR Incentive Program distinguishes between an eligible hospital and an eligible professional ("EP"), which is defined as a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor.[3] Eligible professionals are collectively referred to herein as "physicians".

While hospitals may choose to participate in both the Medicare and Medicaid EHR Incentive Program, physicians may only participate in one and must choose to participate in either the Medicare or the Medicaid EHR Incentive Program.[4] The Medicare EHR Incentive Program provides maximum incentive payments to physicians of $44,000 over five years.[5] The Medicaid EHR Incentive Program provides maximum incentive payments of $63,750 over six years.[6]

The EHR Incentive Program is the carrot to entice physicians to transition to the adoption and use of EHRs. The stick: starting in 2015, physicians will be subject to financial penalties under Medicare if they do not demonstrate meaningful use of EHR technology. Physicians who are not meaningful users of EHR by 2015 will be penalized 1% of their Medicare payments, increasing to 2% in 2016 and possibly reaching as high as 5% in subsequent years.[7] There are no similar penalties under Medicaid. However, the Centers for Medicare & Medicaid Services (CMS) has advised that physicians who participate in the Medicaid Incentive Program are still subject to the Medicare penalties if they treat Medicare patients and have not established meaningful use of certified EHR technology.[8]

As of March 1, 2015, more than 525,000 healthcare providers have registered to participate in the Medicare and Medicaid EHR Incentive Programs and more than 438,000 have received an incentive payment. As of the end of 2014, 95% of eligible hospitals have successfully demonstrated meaningful use of certified EHR technology, while only 62% of eligible physicians have demonstrated same.[9]

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Compelled Examination of Florida licensees: What Constitutes a "Reasonable Place"?

By Jon Pellet[1]

Two recent cases at the Division of Administrative Hearings (DOAH Case Nos. 15-0962 and 15-0611) involved efforts by the Department of Health ("Department") to compel a mental or physical examination of licensees during disciplinary proceedings brought against them for their inability to practice their profession with reasonable skill and safety to patients. In one case, the Department sought to compel a Florida licensed physician to attend an examination at a significant distance from the physician's location (two of the evaluators were located outside of the State of Florida (Kansas and Texas) and the third was located 356 miles away from the licensee in Coral Gables).[2] In the other case, the Department sought to compel a pharmacist to attend an examination in West Palm Beach where she had previously resided even though she now resided in Ohio.[3] In both cases, the Administrative Law Judges ("ALJs") granted the Department's requests for an order compelling examination. The licensee has not challenged or moved to quash the ALJs' Orders in either case and the Department has not sought enforcement of the ALJs' Orders in circuit court. Neither licensee has contested to the reasonableness of the location for the examination or conditions for the examination. However, the two orders raise questions on whether the Department could in fact obtain the relief it seeks from an ALJ in the event of enforcement in the circuit court and objection from the licensees that the orders do not comport with the standards of Rule 1.360(a)(1)(A), Florida Rules of Civil Procedure. It is an open question whether the orders comply with the requirements of Rule 1.360.

It is clear the state has a "compelling interest in the regulation of the practice of [health care providers] within its boundaries in order to protect the health, safety and welfare of its citizens."[4] At least one of the two ALJs issuing the order compelling examination felt that a licensee's voluntary removal from practice was not sufficient to defeat the motion for order compelling examination.[5]

The Department can compel a licensee to submit to a mental or physical examination by physicians designated by the Department when the State Surgeon General or his designee has probable cause to believe a licensee is "unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition.[6]" There are no conditions required by statute for the time, place, manner, and scope of the examination. However, "[i]f the licensee refuses to comply with the order, the department's order directing the examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business.[7]" The summary procedure outlined in Section 51.011, Florida Statutes, applies to proceedings seeking enforcement of the State Surgeon General's order compelling mental or physical examination of a licensee.[8] It is unknown what the circuit court would do if the Department seeks enforcement. In the absence of such guidance, it may look to the standards of Rule 1.360, Florida Rules of Civil Procedure, in determining whether the Department's Order should be enforced.

If the licensee refuses to submit to the compelled examination, in addition to facing potential circuit court enforcement of the order, he or she faces the possibility that the Department will use its summary authority to suspend the license rather than compel the examination.[9] The licensee cannot refuse to submit to examination on the basis that it would violate his or her right to stay silent under the Fifth Amendment to the U.S. Constitution.[10]

A [health care provider] may not both refuse to submit to a mental or physical examination to demonstrate his fitness to practice, and yet demand that he receive the benefits of the status of being a licensed [provider]. He may not by his asserting the privilege either diminish his obligation to the public to establish his fitness, or escape the consequences imposed by the state of Florida for failing to satisfy that obligation. Thus, we find it is constitutionally permissible to deny authority to practice [a health care profession] to a [provider] who asserts the privilege against self-incrimination if his claim has prevented full assessment of his fitness and competency to practice… We find that state authorities, upon a finding of probable cause, may in the course of a bona fide assessment of a [provider's] fitness to practice [a healthcare profession] require that the

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Anatomy of a HIPAA Breach: Counseling Your Client Through the Investigative and Reporting Process

By: Lani M. Dornfeld, Esq.[1]

A HIPAA breach or alleged breach[2] affecting your health care "covered entity" client can result in catastrophic consequences, including not only costly investigative, analysis, reporting and mitigating actions, but potentially costly fines and penalties, loss of patients, loss of personnel involved in the breach and reputational harm. Assisting your client in navigating its way through the investigation and aftermath includes counseling your client on how to reduce these potential harms and losses.[3]

Although the media focuses on massive technology breaches affecting hundreds or thousands of individuals, the most prevalent breaches involve only one or several individuals and most commonly are the result of lack of proper training and re-training, inadvertence, human error and curiosity. Even these smaller breaches, however, require tremendous resources to manage. Some case examples include:[4]

A staff member of a medical practice discussed HIV testing procedures with a patient in the waiting room, thereby disclosing protected health information to others in the room.

A radiology practice submitted a worker's compensation claim for radiology reading services, including the test results, but the patient was not covered by worker's compensation and had not identified that carrier as responsible for payment.

A medical practice mistakenly faxed a patient's medical records to the patient's employer rather than the patient's new health care provider.

A pharmacy employee placed a customer's insurance card in another customer's prescription bag.

A hospital employee's supervisor accessed, examined and disclosed the employee's medical record, without authorization.

Quick Action. Swift action is essential in assisting your client to reduce its exposure. A breach is deemed "discovered" by the covered entity as of the first day on which the breach is known to the organization, or, by exercising reasonable diligence would have been known to the organization.[5] You should counsel your client to assemble its investigative and response team as soon as possible. For small covered entity clients, this may be only the HIPAA privacy officer and/or HIPAA security officer, in conjunction with legal counsel. For larger covered entity clients, the team may include these individuals as well as a "HIPAA compliance committee" or similar oversight body, in conjunction with legal counsel. Typically, it is advisable to ask the privacy officer to take the lead and act as the main point of contact. Board of trustees or board of directors involvement may also be necessary, depending upon the hierarchical structure of your client. Outside forensic information technology experts may also be necessary if the breach involves large-scale electronic health information, for example, a breach in a firewall or loss of a handheld device containing large amounts of patient information. For perceived large-scale breaches, the "response" team may also include in-house or outside public relations professionals.

Investigation. The breach investigation is the cornerstone of all actions to follow, and, as such, requires a careful, planned approach and execution. Since potential breaches can range from a simple wrongly addressed envelope containing protected health information to broad-scale security incidents, investigative steps will naturally flow from the breadth of the potential breach. If cloaking the investigation in the attorney-client privilege will be beneficial to your client, you should counsel your client about how to manage the flow of information in order to maintain the privilege.

Many breach allegations, complaints or discoveries are related to matters such as wrongly addressed mail, disclosure of protected health information without proper written authorization and improper oral or written disclosures such as employees who tell their friends about a patient incident, either in friendly conversations, in email or on social media. Typically, these allegations require, at a minimum, a series of interviews to assess whether information was improperly disclosed and the extent of any disclosure. You may want to counsel clients to have the privacy officer conduct the interviews individually, in a private area, and with a second individual present for purposes of assisting in gathering facts and assessing the veracity of the interviewee. Questions should be focused on the who, what, when, where and why of the incident(s) or allegation(s) and should also be tailored in such a way as to gather information necessary to perform the required HIPAA risk assessment, as further detailed below. In addition to interviews, it may be necessary to obtain copies of emails, copies of mail, information contained in the covered entity's information systems and copies of social media posts and other external items.

Depending on the breadth of electronic breaches, assistance of forensic information technology experts may be necessary. Thus, in addition to gathering the foregoing information, the focus will be on whether and how the client will able to trace and determine the scope of the breach and the individuals whose information was or may have been improperly disclosed.

As early in the investigative process as possible, the covered entity should be seeking to take mitigating actions to contain the breach or prevent additional or future similar breaches. This will be of assistance in assessing the risk and reducing liability exposure. By way of example, if the initial investigation results reveal the disclosure occurred due to inaccurate information contained in the provider's electronic medical record or billing systems, action should be taken to correct the information in all system locations. If it is believed the disclosure occurred due to an electronic system weakness, information technology experts should take remedial steps to reinstitute protective mechanisms.

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Risk Assessment. Once the investigation is complete, you and your client will use the information gathered, as well as any mitigating measures that were instituted thus far, to perform the risk assessment required under HIPAA.[6] Any "acquisition, access, use or disclosure of protected health information in a manner not permitted under subpart E [of the Privacy Rule] is presumed to be a breach," unless, through the performance of a risk assessment, the covered entity "demonstrates that there is a low probability that the protected health information has been compromised."[7]

This determination is made by analyzing at least the following four factors:[8]

The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification. To assess this factor, consider the types of protected health information involved, such as whether the impermissible use or disclosure involved information that is of a more sensitive nature. For example, with respect to financial information, this includes credit card numbers, Social Security numbers or other information that increases the risk of identity theft or financial fraud. Sensitive health information might include an HIV diagnosis or substance abuse treatment records.

The unauthorized person who used the protected health information or to whom the disclosure was made. To assess this factor, consider whether the unauthorized person who received the information has a legal or other obligation to protect the privacy and security of the information.

Whether the protected health information was actually acquired or viewed. This factor requires analysis of whether the information was actually acquired or viewed, versus whether there existed only the opportunity to do so. For example, if a laptop computer was stolen and later recovered and a forensic analysis shows the protected health information was never accessed, viewed, acquired, transferred or otherwise compromised, you may conclude the information was not acquired or viewed, even though the opportunity may have existed. On the other hand, if the covered entity mailed patient information to the wrong address and the recipient called to advise of the error, then, in this case, the unauthorized individual acquired and viewed the information.

The extent to which the risk to the protected health information has been mitigated. The covered entity should attempt to mitigate the risks to the protected health information following any impermissible use or disclosure, such as by obtaining satisfactory assurances that the information will not be further disclosed (through a confidentiality agreement or similar means) or will be destroyed, and should consider the extent and efficacy of the mitigation when determining the probability that the protected health information has been compromised.

After analyzing all factors against the information received in the investigation, you should assist your client in making a determination about whether protected health information has been compromised. If, after analysis of the information, the covered entity determines that there is a low risk that protected health information has been compromised, then no notification is required to be made. If, however, the organization cannot determine there is a low risk, then notification to affected individuals must be made. Notification. Notice to affected individuals must be made "without unreasonable delay" but in no case later than 60 calendar days after "discovery" of the breach.[9] The breach notice must be in plain language; it must describe the types of protected health information involved in the breach; it must list the steps the affected individual should take to protect himself or herself from potential harm resulting from the breach; it must have a brief description of what the organization is doing to investigate the breach, mitigate the harm and protect against further breaches; and, it must include the organization's contact information so that affected individuals can ask questions or obtain additional information.[10] Media notification is also required for a breach involving more than 500 residents of a state or jurisdiction, and the Secretary of the Department of Health & Human Services must be notified in the event of a breach involving 500 or more individuals.[11]

Follow-Up Actions and Other Considerations. The breach investigation and notification actions are typically not the end of the matter. You should counsel your client on implementing necessary staff discipline, education or re-education. Your client should also review and potentially update its HIPAA policies and procedures and change operational processes to protect against reputational harm. In extreme cases of deliberate and malicious breaches and disclosures, referral of the matter to criminal authorities may be warranted. In other instances, you may determine that an in-person apology is warranted, in addition to the mandatory disclosure letter. If a complaint is made to the Office for Civil Rights (the HIPAA oversight authority), the Office will require production of this type of information and will take it into consideration when making its determination on potential

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sanctions. All actions taken by the organization should be well documented and maintained in the official files of the organization's HIPAA privacy officer.

Endnotes

1 Ms. Dornfeld is a Member in the law firm of Brach Eichler L.L.C., with offices in Palm Beach, FL, Roseland, NJ and New York City. She practices in the firm's health law practice group, representing a broad array of health care providers in transactional and regulatory matters including corporate compliance and HIPAA compliance.

2 The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996), codified at 42 U.S.C. § 300gg, 29 U.S.C § 1181 *et seq.* and 42 U.S.C. § 1320d *et seq.* Regulations are found at 45 C.F.R. § 144 (Purpose & Definitions), 45 C.F.R. § 146 (Requirements for Group Health Ins.), 45 C.F.R. § 160 (General Adm. Requirements), 45 C.F.R. § 162 (Transaction Standards and Security Regulations), 45 C.F.R. § 164 (Security and Privacy Regulations). *See* 45 C.F.R. § 164.402 for the definition of a "breach" under HIPAA.

3 Although HIPAA contains requirements for breaches by business associates of covered entities, the focus of this article is on breaches at the covered entity client.

4 *See* http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/allcases.html, for U.S. Department of Health & Human Services case examples.

5 *See* 45 C. F.R. § 164.404.

6 *See* 45 C.F.R. § 164.402.

7 *Id.*

8 *Id.* and commentary at 78 Fed. Reg. 5565, 5642-5644 (1/25/13). Note that a covered entity may choose to notify affected individuals without performing a risk assessment, it if so desires. The point of the risk assessment is to determine whether notification will be *required*.

9 There is an exception in cases where a law enforcement official informs the organization that notification would impede a criminal investigation or cause damage to national security.

10 *See* 45 C.F.R. § 164.404. Note that many states, including Florida, have breach notification statutes that must also be consulted. *See, e.g.,* Fla. Stat. § 501.171 (Florida Information Protection Act of 2014).

11 *See* 45 C.F.R. §§ 164.406 and 164.408. Instructions and the form for submission to the Secretary may be found at http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html. Note that breach incidents involving less than 500 individuals must be reported on an annual basis. *Id.*

10-Questions for Donna L. Lewis, Vice President, Chief Compliance Officer / Privacy Officer at Broward Health

By: Nicholas W. Romanello, Palm Springs

***Author's Note**: For more than 10 years, I have enjoyed a different perspective on the practice of health law. As the general counsel of the Health Care District and the Florida Department of Health, I have had the privilege of working with many of the Health Law Section's most experienced members. Be it Code 15s, rule challenges, mergers and acquisitions or emergency suspension orders, I have been fortunate to observe some of the best health lawyers in action. As the liaison to outside counsel (and the one who reviews monthly invoices) my sense is that the very best lawyers all share a common trait – an acute appreciation of the needs of the client. Harder to find is the attorney who understands the intricacies of the client's operations for example its bond rating and revenue cycle. In an effort to enhance the membership's sensitivity to the client's perspective, it is important to obtain the thoughts and concerns of those we represent. This note is the second in a series I hope to continue. Recently, I spoke to Donna L. Lewis, the Vice President/Chief Compliance Officer and Privacy Officer at the North Broward Hospital District a/k/a Broward Health. In terms of a disclaimer, I had the privilege of working with Ms. Lewis at the Health Care District of Palm Beach County from 2009 through 2011.*

On a recent Friday afternoon, my Compliance Officer sheepishly poked her head in my office and asked if I could join her and the CFO for a moment. While these sort of impromptu meetings seldom end well, this one proved to be a false alarm. This otherwise benign encounter started me thinking generally about compliance and more specifically about one of the women who helps set the standards by which all other compliance officers in Florida are measured: Donna Lewis.

Corporate compliance, of course, is the function that is responsible for the management and oversight of compliance issues within a healthcare organization and which ensures that an organization adheres to and complies with those federal and state regulatory requirements which control operational activities. From the Health Insurance Portability and Accountability Act and Medicare Conditions of Participation to fraud prevention and education, corporate compliance is playing a more prominent role in the healthcare industry. Few in Florida are more experienced in their approach to corporate compliance than Donna Lewis.

Donna is a seasoned executive with more than 20 years of health care industry experience including 15 years in corporate compliance. She has a solid understanding and strong working knowledge of healthcare compliance, including implementing corporate integrity agreements, hospital management and operations. For past 4 years, Donna has served as the Vice President / Chief Compliance Officer and Privacy Officer for the Broward Health ("BH") system in greater Fort Lauderdale. BH is one of the ten largest public hospital systems in the U.S. With more than 7,000 employees, it is one of the largest employers in South Florida. BH services all segments of the community through its 5 hospitals, children's hospital, 7 primary care centers, 4 Family Health Places, 8 school-based clinics, specialty care programs, home-health services, health education programs, free and low-cost screenings, and business partnerships. Her colleagues describe Donna as a "triple threat" in the compliance arena: as a registered nurse she understands quality and standards of care, her MBA from the University of Miami allows her to drill down into profit and loss statements, revenue cycles and compensation methodologies and, most importantly, she has a friendly demeanor which disarms even the most recalcitrant managers.

With 5 hospitals, 2 outpatient centers, 3 urgent care centers and physician's offices, what has this week been like?

It has been an extremely busy week as usual. There is literally something new every hour. It can be a physician requesting clarification on medical directorship log documentation requirements to conducting an investigation to preparing for a series of meetings.

Give us a sense of what the compliance function at BH looks like?

We are in the process of decentralizing our program to better meet the needs of our system which takes a lot of careful planning and implementation. Our budget has increased from 9 FTEs to 16. I am currently looking for a Project Management Professional to partner with me to ensure all of our compliance initiatives and strategies are implemented timely, accurately and documented appropriately. We have deployed regional compliance managers, which is a newly created position to ensure there are boots on the ground and that there is a strong compliance presence within our region(s)/facilities. Standardization and consistency is critical here at Broward Health. All our investigations/audits/tracking of issues and responses are maintained in centralized database.

What is the most challenging aspect of your position?

The ever changing laws and the personalities of people I encounter along the way.

BH has a new CEO (Nabil El Sanadi was appointed CEO in December 2014). Has this changed the compliance function at BH? If so, how?

Yes, it absolutely has changed. Dr. El Sanadi is a forward thinking leader with a cutting edge approach. He is 100% committed to compliance 100% of the time. Since becoming President/CEO, he has challenged me to continue to develop the program with a strategy to ensure compliance through 2030 and beyond. His support of the program has been unbelievable. I look forward to coming to work every day to be challenged with new opportunities.

Talk about engaging outside counsel for compliance issues – is that something that your office does directly or through general counsel?

Any outside counsel is engaged through General Counsel, I do however, have the authority to seek counsel without interference if a critical issue is identified or if a conflict is identified.

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10 QUESTIONS

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Tell me what you look for when hiring an attorney?

Personally, it starts with integrity and trust. I have always enjoyed working with compliance counsel that is competent in health care compliance, provides consistent guidance in writing, and is accountable and responsive. I also like to partner with counsel that can have fun at work and likes to laugh because when times get really tough, a good laugh makes it better.

What do you see as the future of compliance in the hospital industry?

I see more regulations, more settlements and compliance being at the table more, early and often. Although compliance is separate from operations, it is critical to be part of planning for ongoing success.

Let's indirectly acknowledge the 500-pound gorilla in the room, as the DOJ continues its inquiry of BH what advice can you provide hospitals under federal investigation?

I am unable to comment at this time.

(Consistent with her reputation as uber-savvy, Lewis politely declines to answer even the most remote question associated with the federal government's ongoing investigation as to whether BH submitted false Medicare and Medicaid claims. The federal probe has cost BH more than $10M in legal fees and may ultimately result in potential liability of $100M in civil penalties[1]. Lewis, who returned to BH after the start of the federal inquiry, is widely credited for enhancing the culture of compliance for the BH system.)

Healthcare is something of a family business for the Lewis'. What advice has the compliance officer mother given to the pharmacist son?

I am so proud of my son and have told him to understand and know the policies and procedure that affect his job. I've encouraged him to read journals, actively participate in pharmacy associations most importantly to know how to report compliance issues in his workplace.

With Teresa Giudice now doing time for bank, mail, wire and bankruptcy fraud, which Real Housewife is now the most entertaining?

I still believe that Teresa will make a comeback. My current favorite is NeNe from Real Housewives of Atlanta. Every week she has a different wig and every week it gets worse. It is the best stress reliever to watch reality TV!

Nicholas W. Romanello *is the General Counsel and Chief Legal Officer of the Health Care District of Palm Beach County which provides health coverage for low-income residents, a nationally acclaimed trauma system, clinics with a dedicated nurse in more than 170 public schools, a pharmacy network, a long-term skilled nursing and a rehabilitation center, a network of federally qualified health centers and acute care hospital services at Lakeside Medical Center, the county's only public hospital. The interpretations of law and opinions contained in this note are personal to the author and not those of the Health Care District of Palm Beach County, its Board of Commissioners or executive management and staff. He can be reached at 561.659.1270 and nromanel@hcdpbc.org.*

Endnotes

1 Christensen, D. (2015, March 9). Embattled Broward Health paid law firm $10.2 million; tab includes lawyer's M&Ms. Miami Herald.

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[provider] submit to mental or physical examinations to demonstrate his fitness, and may order his discharge if he declines.[11]

Once an evaluation has taken place under Order of the State Surgeon General, if the examination suggests the licensee is unable to practice with skill and safety, if not otherwise resolved, it is probable the Department will file a formal complaint for violation of Section 456.072(1)(z), Florida Statutes.[12] Following the filing of a formal complaint, if the licensee disputes the Department's assertion, the case will be referred to the Division of Administrative Hearings ("DOAH") for assignment to an ALJ for a hearing under Sections 120.57(1) and 120.569, Florida Statutes.

In DOAH Case 15-0962, the licensee had submitted to examination by the Department in September 2013 and had been found unable to practice with skill and safety to patients. The license was not suspended then by emergency order. However, in June 2014, the Department filed a formal complaint seeking disciplinary action against the license for being unable to practice with skill and safety to patients. Then on February 19, 2015, the Department referred the case to DOAH for a hearing. On March 4, 2015, the Department moved to compel an examination of the licensee. An Order granting the Department's motion was entered on March 12. In seeking reconsideration of the Order, the licensee argued that she resided in Ohio and would submit to examination in Ohio. Later, she consented to examination in West Palm Beach but could not agree on the date of the examination. Eventually, a new Order was entered setting the examination for West Palm Beach on April 22, 2015. The formal hearing was continued and as of the time of this article, the case was still pending.

In DOAH Case No. 15-0611, the licensee had voluntarily undergone an evaluation in Kansas in July 2014 through the Department's impaired practitioner consultant but then had failed to comply with the consultant's recommendations.[13] A formal complaint was filed in July 2014 alleging the licensee was unable to practice with skill and safety to patients. On October 21, 2014, before any hearing was held on the complaint, an order was entered by the Department preventing the licensee from practicing medicine until the Professionals Resource Network ("PRN") determined he was safe to practice medicine. On February 4, 2015, the matter was referred to DOAH for a hearing. On March 27, 2015, the Department moved for an order compelling examination. It was opposed by the licensee. However, on April 6, 2015, the ALJ granted the motion but did not designate the examining physician, date of examination, place of examination, conditions, nor scope of examination.

At the DOAH hearing, a question might arise as to whether the Department can use its own authority under Section 456.072(1)(z), Florida Statutes, to compel

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another mental or physical examination or whether it must use the process outlined in Rule 1.360, Florida Rules of Civil Procedure to obtain an Order from the ALJ compelling the examination?[14] Two lines of cases suggest that the Department can only rely on Rule 1.360, Florida Rules of Civil Procedure to obtain another "compelled mental or physical examination" as a means to gather evidence for use at the hearing. Under *Boedy #2*,

> [s]o long as state authorities do not derive any imputation of guilt from a claim of the privilege[15] or use the testimonial revelations gleaned from the [provider] in any other proceeding, there occurs no harmful incriminatory abuse of the information extracted from the [provider during the examination]. Under section [456.072(1)(z)], Florida Statutes, neither the testimony received from a [provider], nor the orders subsequently entered on the basis of that testimony may be used against the [provider] in any other administrative, civil or criminal proceeding.[16]

Secondarily, under Section 120.569(2)(a), Florida Statutes, the Department can only act as a party litigant while DOAH has jurisdiction over the proceeding.[17] Consequently, in a disciplinary proceeding, once the matter is at DOAH, the Department must utilize Rule 1.360, Florida Rules of Civil Procedure, to compel an examination of the licensee. In each of the questioned DOAH cases, the Department sought to use Rule 1.360 to obtain an order compelling examination of the licensees.

Unlike Rule 1.360, Section 456.072(1)(z) places no conditions or limits on the State Surgeon General other than requiring a finding of probable cause to support the order compelling examination. In utilizing Rule 1.360, the Department must first establish that the licensee's mental or physical condition is in controversy and that there is good cause for the examination. "The two essential prerequisites that must be clearly manifested are: (1) that petitioner's mental condition is 'in controversy' i.e. directly involved in some material element of the cause of action or a defense; and (2) that "good cause" be shown i.e. that the mental state of petitioner, even though 'in controversy,' cannot adequately be evidenced without the assistance of expert medical testimony."[18] The landmark case which interpreted the 'in controversy' and 'good cause' requirements (under Federal Rule of Civil Procedure 35(a) which is nearly identical to Fla.R.Civ.P. 1.360(a)) was *Schlagenhauf v. Holder* where the court held that the 'in controversy' and 'good cause' requirements of Rule 35:

> . . . are not met by mere conclusory allegations of the pleadings nor by mere relevance to the case but require an affirmative showing by the movant that each condition as to which the examination is sought is really and genuinely in controversy and that good cause exists for ordering each particular examination.[19]

In both DOAH cases, the Administrative Complaints established that the mental or physical condition of each licensee was in controversy but it is an open question whether good cause was shown.

Even where the licensee's mental or physical condition is in controversy and there is good cause for the examination, the request by the Department must specify "a reasonable time, place, manner, conditions, and scope of examination and the person or persons by whom the examination is to be made.[20]"

Pertinent to the two cases at issue, a reasonable place has been held to mean the resident county or state of the person being examined.[21] An adjoining county has been found acceptable as a reasonable place for examination.[22] In neither DOAH case did the licensee question the reasonableness of the place of examination or compliance with Rule 1.360. However, if they had done so, it is probable that the orders would have been quashed or likely would not be upheld in enforcement proceedings.

Endnotes

1 ***Mr. Pellett** is employed as in-house legal counsel – managing attorney for the Medical Investigation Defense Unit of the Doctors Company where he assists Doctors Company members with disciplinary proceedings before the various state licensing boards, and other regulatory agencies including proceedings before the EEOC, Medicare, and Medicaid, and in staff privilege matters. He can be reached at JPellet@thedoctors.com.*

2 *See* DOAH Case 15-0611.

3 *See* DOAH Case 15-0962.

4 Boedy v. Dep't of Prof'l Regulation, 463 So. 2d 215, 218 (Fla. 1985).

5 *See* Order entered on April 6, 2015 in DOAH Case 15-0611 citing to Boedy v. Dep't of Prof'l Regulation, 433 So.2d 544 (Fla. 1st DCA 1983) (an inactive license is no defense to discipline because it can be reactivated at any time).

6 Fla. Stat. § 456.073(1)(z).

7 *Id.*

8 *Id.*

9 *See* Fla. Stat. §§ 120.60(6) and 456.073(8).

10 *Vining v. Fla. Real Estate Comm'n*, 281 So.2d 487 (Fla. 1973); *Kozerowitz v. Fla. Real Estate Comm'n*, 281 So.2d 487 (Fla. 1973) (A licensee has the right to stay silent in disciplinary proceedings under the Federal and Florida Constitutions and not be compelled to testify or give a sworn answer to a complaint).

11 Boedy v. Dep't of Prof'l Regulation, 463 So. 2d 215, 218 (Fla. 1985) hereinafter referred to as "Boedy #2."

12 If the licensee complies with a request to withdraw from practice and complies with the directives of the impaired practitioner consultant, the case may never result in a public order of discipline. *See* Fla. Stat. § 456.076(4). If the licensee does not comply, the disciplinary process outlined under Section 456.073 will apply.

13 See Fla. Stat. § 456.076. In Florida, the Department of Health contracts with the Professionals Resource Network ("PRN") as one of two impaired practitioner consultants.

14 Fla. Stat. § 120.569(2)(f) provides for discovery in the manner provided by the Florida Rules of Civil Procedure. An order compelling discovery including examination may be enforced in the circuit court pursuant to Fla. Stat. § 120.569(2)(k). See also, Carrow v. Dep't of Prof'l Regulation, 453 So. 2d 842 (Fla. 1st DCA 1984) (non-compliance with circuit court's order upholding subpoena following enforcement must be shown before discipline for failure to comply with lawful subpoena can be imposed).

15 *Boedy* concerned a physician's assertion of his right to remain silent under the Fifth Amendment versus the State's interest in determining his fitness to practice. The Florida Supreme Court found that Dr. Boedy could not assert his right to stay silent and at the same time be permitted to continue practicing medicine.

16 Supra n. xi at 218.

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Becoming a "CLAS act" healthcare provider: complying with National Cultural and Linguistic Health and Healthcare Service Standards

By James Barclay[1]

Medical communication errors are rampant and present significant liability exposure for medical professionals in Florida. For example:

Instructions on medications to "take one tablet *once* a day" can mean taking *11* tablets a day to Hispanics.

A child saying "se pregó", meaning she fell off her trike, can be taken by medical professionals as meaning she was hit by someone.

A young Hispanic who ate something that made him feel like he was intoxicated told ER personnel "estoy intoxicado", which was taken to mean "intoxicated or drug overdose". As a result, treatment and care were delayed resulting in a $71 million malpractice settlement.[2]

Recent failure by a healthcare facility to provide aids and services for deaf and hard of hearing resulted in a voluntary resolution agreement and a $45,000 fine.[3]

Liability exposure for medical communication errors[4] can be reduced or perhaps eliminated by complying with National Cultural and Linguistic Health and Healthcare Service Standards[5] ("CLAS") issued in 2013. Here's why: Diversification of the US population has increased over the years but demographic characteristics of the healthcare workforce have not. As a result, access and equity have decreased while disparity of healthcare has increased thus creating significant liability and exposure for treating patients without understanding cultural backgrounds and languages.[6] The wide variety of populations in Florida, particularly South Florida, and liabilities for failing to address their culture and linguistics make this a vibrant topic of significant importance.

Members of the Health Law Section should advocate that their clients plan and implement resources for providing culturally and linguistically appropriate services – "CLAS act". Doing so will advance health equity, improve quality and help eliminate healthcare disparities and certainly complies with the spirit of reducing discrimination[7] affecting Limited English Proficient Persons[8].

2000 U.S. Census data revealed significant increases in minority and foreign-born populations across the United States. California's "minority" populations became the majority in 1999,[9] and many other states not historically perceived as racially or ethnically diverse are yearly receiving thousands of newcomers from around the globe.

Increasing diversity brings with it a host of opportunities and challenges that are experienced with increasing frequency and immediacy in healthcare facilities, from small rural clinics to large urban medical centers. Sensitivity, empathetic listening, and a little extra effort can often go a long way to bridge the gap between the staff of healthcare organizations and patients who bring cultural differences to the health encounter.[10] The notion of cultural competence has been promoted for many years as a way for healthcare providers and healthcare organizations to understand and respond effectively to the cultural and linguistic needs brought by patients to the healthcare encounter.

By 2050, the US population is projected to be 47% non-Hispanic White, 29% Hispanic, 13% Black and 9% Asian. Today, about 20% of the population, about 58 million people, speaks a language other than English at home and of those almost half have limited proficiency in English.[11] Similar changes are not being seen in the healthcare workforce consequently widening the cultural gap that already exists between healthcare professionals and consumers. Infusion of diverse cultures and languages into today's demographics requires healthcare providers to address these National "CLAS Act" standards.

CLAS planning tips

CLAS standards need not be addressed in their numerical order.

No single planning approach to CLAS will fit every provider.

CLAS can reduce malpractice liability.

Planning for CLAS involves provider leadership at all levels.

CLAS act standards are comprised of three themes under a principal standard: Provide effective, equitable, understandable, respectful and quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy and other communication needs. These themes include "Governance, Leadership and Workforce"; "Communication and Language Assistance" plus Engagement, Continuous Improvement and Accountability". Themes use key terms such as "certified interpreter", "communication needs", "community needs assessment"; several definitions involving culturally and linguistically appropriate competency and services; culture, ethnicity, healthcare disparities, health equity, language assistance services, race, threshold population and vital documents.

CLAS standards are intended to advance health equity, improve quality and help eliminate healthcare disparities by establishing a blueprint for health and healthcare organizations to:

1) *Provide effective, equitable, understandable and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy and other communication needs.*

2*) Advance and sustain organizational governance and leadership that promotes CLAS and health equity through policy, practices and allocated resources.*

3) *Recruit, promote and support a culturally and linguistically diverse governance, leadership and workforce that are responsive to the population in the service area.*

4) *Educate and train governance, leadership and workforce in culturally and linguistically appropriate policies and practices on an ongoing basis.*

5) *Offer language assistance to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate*

continued, next page

timely access to all healthcare and services.

6) Inform all individuals of the availability of language assistance services clearly and in their preferred language, verbally and in writing.

7) *Ensure the competence of individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided.*

8) *Provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.*

9) *Establish culturally and linguistically appropriate goals, policies and management accountability, and infuse them throughout the organizations' planning and operations.*

10) *Conduct ongoing assessments of the organization's CLAS-related activities and integrate CLAS-related measures into assessment measurement and continuous quality improvement activities.*

11) *Collect and maintain accurate and reliable demographic data to monitor and evaluate the impact of CLAS on health equity and outcomes and to inform service delivery.*

12) *Conduct regular assessments of community health assets and needs and use the results to plan and implement services that respond to the cultural and linguistic diversity of populations in the service area.*

13) *Partner with the community to design, implement and evaluate policies, practices and services to ensure cultural and linguistic appropriateness.*

14) *Create conflict- and grievance-resolution processes that are culturally and linguistically appropriate to identify, prevent and resolve conflicts or complaints.*

15) *Communicate the organization's progress in implementing and sustaining CLAS to all stakeholders, constituents and the general public.*

Immediate approaches to implementing a CLAS Act program include language-assisted telemedicine, interpretation services,[12] document translation[13] and video conferencing.[14] Doing so should reduce exposure to liability under the

CLAS act, result in more equitable provision of services in a more understandable and respectful way.

Achieving compliance with the principal CLAS act standard can best be accomplished by implementing standards 2-15, keeping in mind that important factors in implementing a successful CLAS act program are competent interpreters, dedicated staff, adequate funding and effective training.

CLAS Act implementation tips*Using a competent interpreter is a key to a successful CLAS Act effort.*

Becoming a CLAS Act provider can improve patient outcomes, patient satisfaction and increase market share.

CLAS planning and implementation tasks must not overlap. Achieving the principal CLAS standard comes with substantially implementing CLAS standards.

Endnotes

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Jimmo v. Sebelius and the Demise of Medicare's "Improvement Standard"

By Paula Bentley, Esq.[1]

On January 18, 2011, the Center for Medicare Advocacy and Vermont Legal Aid filed a historic class action lawsuit on behalf of Glenda Jimmo and four other Medicare beneficiaries against Kathleen Sebelius, the Secretary of Health & Human Services, challenging Medicare's long-standing practice of denying coverage for skilled care and therapy services unless the beneficiary showed a likelihood of improvement.[2] The plaintiffs alleged that Medicare was illegally applying an "Improvement Standard" to discontinue or deny coverage for skilled nursing and therapy services rendered in skilled nursing facility (SNF), home health (HH), and outpatient therapy ("OPT") settings if the beneficiary had stopped improving or Medicare determined that there was no potential for improvement from the services.[3]

The *Jimmo* case was resolved on January 24, 2013, when the U.S. District Court for the District of Vermont approved a landmark settlement agreement (the "Settlement") that required the Centers for Medicare & Medicaid Services (CMS) to take specific steps to clarify that when skilled services are required to prevent or slow further deterioration, Medicare coverage cannot be denied simply because the beneficiary lacks the potential for improvement or restoration.[4] Among other things, the Settlement mandated that CMS revise portions of its Medicare Benefit Policy Manual (MBPM); implement a nationwide educational campaign for contractors, providers, suppliers, and adjudicators; engage in accountability measures to ensure that claims determinations are made in accordance with the correct standards; and implement an appeal process for beneficiaries to seek review of claims that may have been improperly denied.

Medicare beneficiaries most affected by application of the faulty Improvement Standard included patients with long-term, debilitating, chronic conditions such as Multiple Sclerosis, Alzheimer's Disease, Parkinson's Disease, and Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease). Skilled care providers were also negatively impacted by application of the Improvement Standard in those instances where they provided necessary care to maintain a patient's condition and were left unpaid for those services when the Medicare claim was denied.

Neither the Medicare statute nor the implementing regulations mention or suggest an Improvement Standard as a prerequisite to Medicare coverage. The Standard emerged as a result of MBPM provisions that were inconsistent with the regulations on this issue, creating confusion among Medicare contractors. Over time, the Improvement Standard became part of Medicare contractors' internal guidelines in the form of Local Coverage Determinations ("LCDs"), resulting in widespread denial of coverage for skilled services where the beneficiary did not demonstrate the potential for improvement.[5] Health care providers also integrated this standard into their admission, discharge and billing practices. Although CMS has denied establishing a "rule-of-thumb" Improvement Standard for determining coverage for skilled care, it agreed to comply with the Settlement to ensure that future claims would be consistently and appropriately adjudicated in compliance with existing Medicare policy.

The required revisions to the MBPM, which became effective on January 7, 2014, clarified that skilled care may be necessary to: 1) improve a patient's current condition; 2) maintain a patient's current condition; or 3) prevent or slow further deterioration of a patient's condition.[6] The revisions also addressed inpatient rehabilitation facility ("IRF") claims, clarifying that an IRF claim can never be denied because a patient is unable to achieve complete independence or is unable to return to his or her prior level of functioning.[7]

One of the key aspects of the manual clarifications addresses the important distinction between restorative/rehabilitative therapy and maintenance therapy. The purpose of restorative or rehabilitative therapy is "to reverse, in whole or in part, a previous loss of function."[8] Therefore, it is appropriate to consider the potential for improvement when evaluating a claim for skilled therapy that is restorative or rehabilitative in nature. Similarly, in the IRF or comprehensive outpatient rehabilitation facility ("CORF") setting, potential for improvement must be considered because skilled therapy in those settings will only be covered if it is reasonably expected to improve the patient's functional capacity or adaptation to impairments.[9]

On the other hand, coverage for "maintenance therapy" should never be dependent on a beneficiary's potential for improvement. The revised MBPM indicates that maintenance therapy is warranted when an individualized assessment of a patient's condition demonstrates that skilled care is necessary to design, establish or perform a safe and effective program to maintain a patient's current condition or prevent or slow further deterioration.[10] Simply demonstrating the need for a maintenance program is not enough; it must also be shown that skilled care is necessary for the safe and effective performance of that program. Skilled care will only be covered by Medicare if it is determined that: 1) the particular patient's special medical complications require the skills of a qualified therapist or nurse to perform a type of service that would otherwise be considered non-skilled; or 2) the needed services are of such complexity that the skills of a qualified therapist or nurse are required to perform the procedure.[11] If a service can be safely and effectively performed by an unskilled individual, including the patient or a family member, the service will not be considered a skilled service.

The revised MBPM also provides enhanced guidance on documentation to assist providers in their efforts to identify and include the type of clinical information that will allow Medicare contractors to confirm that the patient's needs are complicated and that skilled care is, in fact, needed in a certain case.[12] The manual revisions relating to documentation do not require specific forms or phraseology as a prerequisite

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To understand why so many physicians are struggling with demonstrating their meaningful use of EHR, one must first understand what it takes to demonstrate meaningful use of certified EHR technology.

Meaningful use of certified EHR technology

Certified EHR technology is technology that has been tested and certified in accordance with the criteria established by the Office of the National Coordinator for Health Information Technology ("ONC") as having met all applicable certification requirements adopted by the Secretary of HHS. Certified EHR technology must: (1) include patient demographic and clinical health information, such as medical history and problem lists; and, (2) have the capacity: (i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; and (iv) to exchange electronic health information with, and integrate such information from other sources.[10]

The certification criterion first adopted by the Secretary of HHS for certified EHR technology are known as the 2011 Edition CEHRT. The more recent certification criterion adopted by the Secretary are referred to as 2014 Edition CEHRT.

The goal of the HITECH Act is not just adoption of EHRs by healthcare providers but the use of EHRs by healthcare providers to significantly improve individual patient care and improve population health outcomes. The ONC defines meaningful use as using certified EHR technology to: (1) improve quality, safety, efficiency, and reduce health disparities; (2) engage patients and family; (3) improve care coordination, and population and public health; and (4) maintain privacy and security of patient health information.[11] The overall objectives of meaning use are: (1) better clinical outcomes; (2) improved population health outcomes; (3) increased transparency and efficiency; (4) empowered individuals and (5) more robust research data on health systems.[12]

The EHR Incentive Program has divided meaningful use into three stages. 2011 was the first year for which a healthcare provider could demonstrate meaningful use of EHR technology and receive incentive payments. The stage of meaningful use that a physician is expected to attest to annually depends on when the physician began his or her participation in the EHR Incentive Program.

Stage 1 Meaningful Use contains a total of 23 meaningful use objectives – 13 required core objectives and 10 menu set objectives.[13] The physician must meet the 13 core objectives and 5 of the 10 menu set objectives (a total of 18 required objectives) in order to qualify for an incentive payment.[14] CMS published a list of the core and menu set objectives for physicians' ease of reference.[15] Under Stage 2 Meaningful Use, a physician must meet 17 core objectives and 3 menu objectives from a total list of 6 for a total of 20 required objectives.[16] Additionally, there are clinical quality measures ("CQMs") that are associated with each objective.

Not only must a physician meet the objectives of Stage 1 and Stage 2, but the physician must also demonstrate via an annual attestation, in a manner specified by CMS (or for a Medicaid physician, in a manner specified by the State) that during the EHR reporting period, he or she: (1) used certified EHR technology, specifying the technology used, and (2) satisfied the required objectives and their associated measures.[17] The physician must also provide the result of each applicable CQM for all patients seen during the reporting period. For instance, under Stage 2, a physician must report on 17 core objective, 3 of 6 menu-set objectives, and 9 of 64 CQMs, during the EHR reporting period. A physician must demonstrate Stage 1 meaningful use of certified EHR technology for a minimum period of two years before advancing to Stage 2.[18]

One major difference between Stage 1 and Stage 2 Meaningful Use is that under Stage 2 physicians are required to provide more than 50% of their patients with online access to their health information.[19] Previously, physicians were only required to provide more than 50% of their patients with an electronic copy of their health information. Stage 2 also added a new requirement that physicians use the electronic messaging function of their certified EHR technology to communicate with their patients and at least 5% of their patients must send a secure electronic message to the physician.[20]

With such onerous reporting requirements, it is not surprising that 257,000 physicians faced Medicare reimbursement penalties at the beginning of this year for failing to demonstrate meaningful use of EHR technology.[21]

As of March 2015, of the 353,350 physicians registered with the Medicare Incentive Program, 291,260 had demonstrated Stage 1 Meaningful Use and 38,472 have demonstrated Stage 2 Meaningful Use.[22] Many physicians are faced with demonstrating that they meet Stage 2 Meaningful Use this year. However, a recent joint survey conducted by Medical Practice Insider and SERMO, a social media site for U.S. physicians, found that 55% of physicians do not plan to attest for Stage 2 Meaningful Use in 2015, despite the reduction in Medicare payments they will face for their failure to attest.[23]

Why are physicians refusing to attest to Stage 2 Meaningful Use?

There are two specific reasons why physicians are refusing to attest to Stage 2 Meaningful Use.

First, is the requirement in 2015 that all eligible physicians be required to report using 2014 Edition CEHRT.[24] Originally, physicians were required to use 2014 Edition CEHRT to demonstrate either Stage 1 or Stage 2 Meaningful Use in 2014. However, there were delays in EHR vendors providing certified products, which led to delays in the ability of providers to implement 2014 Edition CEHRT. Due to the delay in available 2014 Edition CEHRT, CMS provided alternatives routes for physicians to demonstrate meaningful use in 2014 without using 2014 Edition CEHRT. However, in order for a physician to utilize one of these alternatives, the physician had to attest that their inability to implement 2014 Edition CEHRT was attributable to the issues related to software development, certification, implementation, testing, or release of the product by the EHR vendor.[25]

The delay in EHR vendors updating to 2014 Edition CEHRT certainly left physicians frustrated. To compound the problem, few of the certified EHR technologies are certified for all 64 CQMs (since physicians must only report on 9) and most are only certified for a fraction of that.[26] This has left many physicians and physician practices in the difficult position of either being subject to their EHR vendors' delays and CQM reporting capabilities that do not mesh with the CQMs that the physician is reporting or switching their EHR vendor at an additional expense.[27] Some physicians

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have decided that obtaining 2014 Edition CEHRT that meets their needs is not worth the headache or the cost and have decided to forego the 2014 Edition CEHRT needed to attest for meaningful use in 2015 or wait for newer and better EHR technologies. [28]

Physicians are also refusing to attest to Stage 2 Meaningful Use because it requires a certain level of patient engagement with and use of health information technology in order for physicians to achieve meaningful use. CMS believes that physicians and hospitals are in the best position to encourage the use of health information technology by patients to further their own health care. [29] As discussed above, core objectives for physicians under Stage 2 Meaningful Use include providing more than 50% of patients with online access to their health information and that more than 5% of patients use the certified EHR technology by sending a secure electronic message to the physician. Patient engagement is an often-cited reason for physicians choosing to forego Stage Two meaningful use attestation.[30] As one doctor explained, "it is almost impossible to do Stage 2. It requires patients to have emails and engage my EHR… I have a lot of patients in their 80s and 90s, they don't have computers, let alone email."[31]

A more general problem with demonstrating meaningful use under the EHR Incentive Program is the added administrative costs. Naturally, the smaller the physician practice, the more difficult it is to demonstrate meaningful use of a certified EHR technology as solo practitioners and small physician practices do not have the time or resources to dedicate to implement a certified EHR technology and meet the necessary reporting requirements to demonstrate meaningful use. As Robert Wergin, M.D., president of the American Academy of Family Physicians, recently testified before the U.S. Senate HELP Committee, family physicians are having a difficult time with Stage Two meaningful use requirements because the "time, expense and effort it takes makes it not worth while."[32] The American Medical Association has also been extremely critical of the meaningful use program and its detrimental effect on physicians.[33]

Is this the end for physicians' meaningful use of certified EHR technology?

Presently, over 535,000 healthcare providers have registered for the Medicare and Medicaid EHR Incentive Programs.[34] Of the approximately 358,000 healthcare providers who are registered with the Medicare Incentive Program, 295,659 have successfully demonstrated Stage 1 Meaningful Use of certified EHR technology.[35] Based on these numbers, and despite the problems Stage 2 Meaningful Use has created for physicians, CMS and ONC are moving full steam ahead. In March, the ONC announced its proposal for 2015 Edition CERHT.[36] Simultaneously, CMS released its proposed rule for Stage 3 Meaningful Use.[37] The public comment period for both ends May 29, 2015. CMS claims that the proposed rule for Stage 3 Meaningful Use simplifies and streamlines the meaningful use reporting requirements.[38] However, at the earliest, Stage 3 Meaningful Use implementation will not begin until 2017.

While the meaningful use program moves forward, for now, many physicians appear to be taking a wait-and-see approach to Stage 2 Meaningful Use. Their position may change as penalties are assessed or better technologies develop.

The federal laws and regulations governing the EHR Incentive Program are convoluted and constantly in flux, which can leave attorneys as frustrated as their physician clients when trying to counsel them. Some practical pointers to keep in mind when advising physician clients:

1. If a physician is selecting an EHR vendor, the physician should be aware of the CQMs they plan to report and confirm that the EHR vendor has certified EHR technologies related to those CQMs.

2. Consider provisions in agreements with EHR vendors that govern liability for lost incentive payments or penalties imposed due to a physicians' inability to attest to meaningful use based on delays in the EHR vendor updating technologies in a timely manner.

3. Because incentive payments and penalties are specific to the physician, employment agreements need to address who is entitled to incentive payments or responsible for penalties.

Endnotes

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> The Meaningful Use program was intended to increase physician use of technology to help improve care and efficiency. Unfortunately, the strict set of one-size-fits-all requirements is failing physicians and their patients. They are hindering participation in the program, forcing physicians to purchase expensive electronic health records with poor usability that disrupts workflow, creates significant frustrations and interferes with patient care, and imposes an administrative burden.
>
> The AMA supported the original HITECH legislation and we have provided extensive and constructive feedback to the Administration to help fix the Meaningful Use program, but few changes have been made. In light of the dismal number of eligible professionals meeting Meaningful Use, we hope that the Administration will now move forward with the solutions… to make the program more successful and better enable physicians to provide quality care for their patients.

34 *Supra* note 22.

35 *Id.*

36 http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations.

37 https://www.federalregister.gov/articles/2015/03/30/2015-06685/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3#h-49.

38 *Supra* note 9.

to coverage, nor do they add any new reporting frequency requirements. However, CMS advises that vague or subjective terminology such as "patient tolerated treatment well," or "caregiver instructed in medication management," does not adequately describe the need for skilled care and must be avoided. Documentation should include objective measurements of physical outcomes of treatment or a clear description of the changed patient behavior due to education programs.[13]

The Settlement also required CMS to engage in a nationwide educational campaign to communicate the clarified maintenance coverage standards to contractors, adjudicators, providers, and suppliers.[14] In addition to distributing written materials, CMS conducted "National Calls" to communicate the policy clarifications to these stakeholders. CMS also revised relevant 1-800-MEDICARE customer service scripts to ensure consistency with the revised MBPM provisions. CMS concluded the required educational campaign on January 24, 2013.

In the final phase of compliance with the *Jimmo* Settlement, CMS agreed to implement accountability measures to ensure that future maintenance therapy claims are decided in conformance with the manual clarifications. CMS is currently engaged in this accountability phase, which involves review of a random sample of SNF, HH, and OPT coverage decisions by independent Medicare contractors to determine overall trends and identify any problems in the application of the clarified standards.[15]

CMS was also required to provide a "re-review" process to allow beneficiaries to resubmit individual claims that were denied due to lack of improvement or the potential to improve.[16] The submission deadline for re-review under the Settlement occurred on January 24, 2015. Although the deadline to request re-review under *Jimmo* has passed, a claim that is improperly denied due to continued application of an incorrect Improvement Standard can still be challenged through the normal CMS appeals process. An appeal can be filed by the beneficiary or the provider and must be submitted within 120 days after the initial denial of the claim by the Medicare contractor.[17]

Despite CMS's publication of the required MBPM revisions and completion of the associated educational campaign, it is likely that many Medicare contractors and adjudicators are still applying the incorrect standard in making claims determinations for skilled maintenance therapy. In fact, plaintiff Glenda Jimmo's claim was submitted for re-review and was denied by the Medicare Appeals Council in April 2014 due to lack of improvement.[18] A second lawsuit was

continued, next page

filed, which was quickly settled in October 2014 with the federal government agreeing to pay the full value of Jimmo's claim plus her attorney's fees.[19] This development certainly raises questions regarding the effectiveness of CMS's educational campaign in dispelling long-standing beliefs regarding the mythical Improvement Standard.

Interestingly, the Settlement did not require CMS to notify or educate Medicare beneficiaries regarding the clarifications to Medicare coverage standards. Thus, most beneficiaries continue to rely on their health care providers to advise them regarding what services will be covered by Medicare. From a patient advocacy standpoint, it is therefore imperative that physicians and other health care providers understand the revised coverage standards so they can accurately educate patients and their families regarding whether a recommended skilled service will be eligible for reimbursement under Medicare.

To facilitate payment for skilled maintenance therapy, it is also essential that skilled care providers develop and maintain documentation that follows the revised MBPM guidelines and clearly supports the need for skilled services to maintain a patient's current capabilities or prevent further deterioration. The following measures may be implemented by skilled care providers to integrate the revised standard into their admission, discharge, and billing practices:

review and revise any policies that may include components of the erroneous Improvement Standard;

educate intake, admissions, discharge and billing staff regarding the MBPM clarifications and the revised maintenance standard, as well as its application to new admissions, current residents or, in the case of HH organizations, new and existing clients;

provide patients and their families or representatives with information regarding the revisions in Medicare coverage requirements for skilled services and direct them to the CMS Ombudsman or the local Long-Term Care (LTC) Ombudsman office for assistance in understanding the revised coverage standards.

Executive Director of the Center for Medicare Advocacy, Judith Stein, expects the *Jimmo* Settlement to facilitate access to basic skilled therapy for millions of Medicare beneficiaries with chronic conditions, ending a 30-year battle to eliminate the "illegal, harmful, and unfair application of the law."[20] Undoubtedly, both Medicare beneficiaries and skilled care providers will benefit from the ultimate demise of the Improvement Standard, but both groups will need to remain vigilant in coming months as CMS contractors and adjudicators gradually adjust to these changes in firmly ingrained Medicare policy.

Endnotes

1 Paula Bentley, RN, JD, LHRM, is a health law attorney in the Tampa office of Gunster, Yoakley & Stewart, PA. Ms. Bentley brings a unique skill set to her practice, being licensed as both a registered nurse and a health care risk manager. Her practice areas include administrative licensure defense, Medicaid and Medicare compliance, and HIPAA and state privacy laws. Ms. Bentley can be reached at pbentley@gunster.com.

2 Jimmo v. Sebelius, Case No. 5:11-CV-17-CR (D. Vt. Jan. 18, 2011). The amended complaint is available at http://www.medicareadvocacy.org/wp-content/uploads/2012/11/Amended-Complaint-FILED.030311.pdf.

3 Id.

4 Jimmo v. Sebelius, Case No. 5:11-CV-17-CR, Settlement Agreement dated Oct. 16, 2012 (hereinafter "Settlement Agreement"), available at http://www.medicareadvocacy.org/ wp-content/uploads/2012/12/Jimmo-Settlement-Agreement-00011764.pdf.

5 See Am. Health Care Ass'n. Memo., "Jimmo v. Sebelius Civil Action No. 5:11-CV-17-CR (D.Vt.) (Final Settlement Approved 1/24/2013)" available at http://www.ahcancal.org/facility_operations/medicare/Documents/AHCA%20 Jimmo%20 Memo.pdf (Feb. 7, 2013).

6 CMS Transmittal 179, Pub. 100-02 Medicare Benefit Policy, "Summary of Changes," available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179BP.pdf (effective Jan. 7, 2014) (hereinafter "Transmittal 179").

7 Id. at Ch.1, § 110.2.

8 Id. at § IV, "Business Requirements."

9 Id. at Ch. 1, §110.2.

10 Id. at § IV, "Business Requirements."

11 Medicare Benefit Policy Man., Ch.7, §§ 40.1.1 and 40.2.2.E (hereinafter "MBPM"). The MBPM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.

12 Transmittal 179, supra n. 5 at § IV.

13 MBPM Ch.7, § 40.1.1.

14 Settlement Agreement at § IX.9.

15 Id. at § IX.17.

16 Id. at § IX.17.e.

17 First Coast Serv. Options, "When to File an Appeal," available at https://medicare.fcso.com/Appeals/ 164098.asp (last modified Mar. 13, 2015); Medicare.com, "How Do I File an Appeal?" available at http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html (accessed Apr. 26, 2015).

18 Erin Mansfield, "Seven Years Later, Vermonter to Get Medicare Payment," Times Argus, available at http://www.timesargus.com/article/20141101/NEWS03/711019980 (Nov. 1, 2014); Lois Bowers, "Jimmo Settlement: Will Effects Be Widespread?" Long-Term Living, available at http://www.ltlmagazine.com/news-item/latest-settlement-brings-good-news-jimmos-medicare-coverage (Nov. 3, 2014).

19 Id.; Jimmo v. Burwell, Case No. 5:14-CV-128-CR, Settlement Agreement, available at http://www. medicareadvocacy.org/ wp-content/uploads/2014/10/Jimmo-II-Settlement-FINAL.pdf (N.D. Ver. Oct. 29, 2014).

20 David Pardo, "Advocacy Group Reaches Accord with HHS to Provide Coverage for Chronic Conditions," Bloomberg Law – BNA's Health Care Daily Report (Oct. 24, 2012) (quoting Ctr. for Medicare Advocacy Exec. Dir. Judith Stein).