Understanding Business Associates

By: Mathew J. Levy, Esq.
Stacey Lipitz Marder, Esq.

Overview:
Throughout a health care provider's career, he/she will often enter into several relationships with third party vendors - billing companies, EMR companies, marketing companies, internet providers, staffing companies and medical device/equipment suppliers to name a few. The relationship between these third party vendors and health care providers is important not only from a business perspective, but also a compliance perspective. These third party vendors often have access to the protected health information of the practice's patients, rendering such vendors as business associates under the Health Insurance Portability and Accountability Act ("HIPAA"). Therefore, it is imperative that health care practices understand the applicable rules and regulations governing the relationship between practices and such vendors, and comply with same. This is especially important in light of the new Health Information Technology for Economic and Clinical Health Act ("HITECH Act")[1], which amended HIPAA, as there are now more stringent requirements which must be met with respect to the relationship between covered entities (including health care practices and providers) and business associates.

What is a business associate?:
As per the HITECH Act, business associates are individuals and entities that are not part of a covered entity's workforce and that engage in activities such as claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; patient safety and repricing, and create, receive, maintain or transmit protected health information to perform certain functions or activities on behalf of a covered entity. Therefore, if a business associate has access to such protected health information, even if it does not view such information, it is considered a business associate and must therefore comply with all applicable rules and regulations. The final rules also indicates that subcontractors (individuals or entities that business associates delegate functions, activities or services other than a member of such business associate's work force) that create, receive, maintain or transmit protected health information on behalf of business associates are now considered business associates. Therefore, all requirements and obligations applying to business associates also apply to subcontractors.

Business Associate Agreements:
Under HIPAA, covered entities were always required to enter into HIPAA compliant business associate contracts with their business associates so that covered entities could obtain "satisfactory assurances" from a business associate that the business associate would appropriately safeguard protected health information. Amongst other things, HIPAA required business associate agreements to contain language identifying permitted and required uses and disclosures, a limitation on the business associate using or disclosing protected health information other than as stated in the business associate agreement or as required by law, and a statement that the business associate would use appropriate safeguards to prevent the inappropriate use or disclosure of protected health information.

As per the HITECH Act, there are additional requirements that must be met with respect to the business associate agreement, including having language indicating that business associate have compliant written security policies and procedures, as well as specifying that business associates must timely report breaches of unsecured protected health information to the covered entity. Furthermore, all business associate agreements should indicate that business associates should enter into agreements with their subcontractors in order to ensure that any protected health information disclosed is adequately protected. As such, it is recommended that such business associate agreements be revised to make certain that the business associates comply with the electronic security rules under HIPAA. Interestingly, under the HITECH Act, business associates are now also required to enter into HIPAA compliant business associate agreements with their subcontractors, although covered entities are not required to enter into business associate contracts with their business associates' subcontractors.

Although HHS now has direct enforcement authority over business associates and subcontractors, business associate agreements are still important in order to have business associates/subcontractors remain contractually liable.

Conclusion:
In sum, health care providers should immediately evaluate their relationships with their vendors, including identifying which vendors constitute business associates in order to ensure that they have compliant business associate agreements in place. That being said, covered entities who have business associate agreements already in place should have their business associate agreements reviewed so that the appropriate amendments can be made if necessary, and those covered entities without business associate agreements in place should have such agreements drafted immediately. In addition to having compliant business associate agreements in place, covered entities need to make certain that their privacy and security policies, as well as HIPAA authorization forms, are compliant, and that their staff is informed of such changes. The federal government has invested a significant amount of money with the Office of Civil Rights (the branch of HSS responsible for enforcement of HIPAA violations), and has indicated that it will be conducting an increasing number of audits in the near future in order to identify instances of non-compliance. Such violations carry steep penalties and health care providers need to protect themselves and their practices so that exposure is limited.

About the Authors:

Mathew J. Levy, Esq. is a Principal of Weiss Zarett Brofman Sonnenklar & Levy, PC. Mr. Levy is nationally recognized as having extensive experience representing healthcare clients in transactional and regulatory matters. Mr. Levy has particular expertise in advising health care clients with respect to contract issues, business transactions, practice formation, regulatory compliance, mergers & acquisitions, professional discipline, criminal law, healthcare fraud & billing fraud, insurance carrier audits, litigation & arbitration, and asset protection-estate planning. You can reach Mathew Levy at 516-627-7000 or email: mlevy@weisszarett.com.

Stacey Lipitz Marder is an associate at Weiss Zarett Brofman Sonnenklar & Levy, PC., with experience representing healthcare providers in connection with transactional and regulatory matters including the formation and structure of business entities, negotiating and drafting contracts and commercial real estate leases, stock and asset acquisitions and general corporate counseling. Ms. Marder also has experience advising healthcare clients on a wide range of regulatory issues including Stark, the Anti-Kickback Statute, fraud and abuse regulations, HIPAA, reimbursement and licensing matters.

[1] On January 17, 2013, the U.S. Department of Health and Human Services (HHS) released the omnibus regulations under HIPAA , including implementing changes made by the HITECH Act (the final rule). The final rule is effective September 23, 2013.

It's Showtime: An analysis of outpatient psychiatric clinic break rates at Richmond University Medical Center with aim to increase treatment adherence.

Authors: Ludmila A; Ali, Z; Yekaterina, A; Andrew, P; Okeleji, A; Ahmad, A;

Background: Poor rates of compliance with follow up remain a significant challenge experienced by all healthcare fields. Significant break rates compromise quality of care, resulting in poor treatment outcomes and financial expenditures. According to a combined study from Clarke Institute of Psychiatry in Toronto and The University of Toronto, break rates can ranged from 15-80%. Psychiatric patients tend to fall on the higher end of this spectrum, perhaps due to the nature of their illnesses, raising concerns about the morbidity and mortality of our patient population.

Last year, our team focused primarily on improving adherence to intake appointments at our Evaluation and Referral (E&R) by providing reminder appointment cards to patients who were evaluated and discharged from our Comprehensive Psychiatric Evaluation Program (CPEP). Data analysis did not reveal favorable outcomes, however, was strongly confounded by an unexpected change of location of E&R office during data collection.

This year, our study attempted to increase adherence to outpatient follow up appointments at RUMC psychiatric clinics, thereby promoting the well-being of our patients and improving financial reimbursement for our institution.

Aim: This study sought to determine the factors associated with missed appointments at RUMC's two outpatient psychiatric clinics – St. George OPD and West Brighton OPD - and propose an intervention to address the most common reasons for non-adherence to follow up.

Method: Beginning in September 2017, monthly patient break rates were calculated for each of three resident physicians (two based in St. George OPD and one in West Brighton OPD). Patients from both outpatient psychiatric clinics were anonymously surveyed regarding their reasons for missed appointments, their preferred modes of communication for appointment reminders from clinic staff, and how often, if at all, they had received reminder phone calls prior to their appointments. Patient surveys were tallied monthly and results were compared between the two outpatient clinics.

Result: Analysis of data collected from patient surveys revealed that one of the most common reasons reported for missed appointment was "did not remember," second only to "feeling unwell." The most commonly reported preferred mode of communication for appointment reminders was via "phone call." Patient surveys regarding prior receipt of reminder phone calls revealed that the majority of patients at the West Brighton OPD have received reminder calls prior to their appointments, while the majority of patients at St. George OPD did not. Break rates at West Brighton OPD were determined to be 5-10% between September 2017 and December 2017 and break rates at St. George OPD were determined to be 25-10% between September 2017 and December 2017.

Conclusion: Aforementioned results suggest that consistent phone call reminders prior to scheduled appointments, as observed in West Brighton OPD, result in significantly lower break rates in the outpatient clinics. It can be further hypothesized based on these results that investing in an automated telephone reminder service (to be implemented in both outpatient clinics) will significantly improve outpatient appointment adherence, thereby promoting positive patient outcomes and preventing revenue lost by the institution to follow-up non-adherence.

Effect of New York State Electronic Prescribing Mandate on Opioid Prescribing Patterns

Dr. Dimitry Danovich

ABSTRACT

Introduction:

Drug overdose was the leading cause of injury and death in 2013, with drug misuse and abuse causing approximately 2.5 million emergency department visits in 2011. The Electronic Prescriptions for Controlled Substances program was created with the goal of decreasing rates of prescription opioid addiction, abuse, diversion and death by making it more difficult to "doctor-shop" and alter prescriptions.

Study Objectives: In this study, we describe the opioid prescribing patterns of emergency medicine physicians after the introduction of the New York State electronic prescribing of controlled substances mandate.

Methods: This was a retrospective, single-center, descriptive study with a pre-/post-test design. The pre-implementation period used for comparison was April 1–July 31, 2015 and the post-implementation period was April 1–July 31, 2016. All ED discharge prescriptions for opioid medications prior to and after the initiation of New York State EPCS were identified.

Results: During the pre-implementation study period, 31,335 patient visits were identified with 1,366 patients receiving an opioid prescription. During the post-implementation study period, 31,300 patient visits were identified with 642 patients receiving an opioid prescription. This represented an absolute decrease of 724 (53%) opioid prescriptions ($p<0.0001$).

Conclusion: There was a significant decline in the overall number of opioid prescriptions after implementation of the New York State electronic prescribing of controlled substances mandate.

RICHMOND COUNTY MEDICAL SOCIETY

REPORT

June, 2018 Summer Edition

Salvatore S. Volpe, M.D.,
FAAP FACP FHIMSS CHCQM
211th President

PRESIDENT'S PERSPECTIVE

It has been a year since I was given the honor to serve as your 211th President and to work with the Society's leadership and general membership on several initiatives. We did our best to move the bar for the Society as our predecessors have done.

Here are the list of initiatives.

1. Foster relationships with other organizations and agencies
2. Re-locate our office to a newer facility
3. Increase membership
4. Enhance the educational value of the Comitia Minora meetings
5. Update the 2008 Bylaws
6. Enhance use of Social Media via the Website, Facebook and Twitter
7. Secure a relationship with a new law firm to represent the Society

First, we strove to fulfill the Society's Mission Statement and in particular: **"to maintain them in appropriate and equitable relationship with the public and with all agencies working in the fields of health and welfare."**

To that end, we shared opportunities to improve and facilitate the practice of medicine from multiple sources including the NYC Department of Health and Mental Hygiene, the Borough President's Office, the Staten Island Performing Provider System, Staten Island University Hospital and Richmond University Medical Center. We also worked collaboratively with the leadership of the other counties on several projects. Making Strides Against Breast Cancer and the Walk to End Alzheimers were added to the annual Autism Speaks Walk.

Recently, we began a tradition of having Community-Based Organizations (CBOs) present their work at our Comitia Minora meetings. Our two most recent presentations were from Person-Centered Care Services (PCCS) and Community Health Action of Staten Island (CHASI). The presenters shared resources that help enhance the quality of life of our patients as well as provide such necessities as food, clothing and therapy for substance use disorder. Our Winter Drive provided much appreciated food and toys for (CHASI).

Second, we re-located our office from the Seaview Hospital Campus to 900 South Avenue which had multiple benefits.

A. 25% reduction in rent and utilities expenses
B. Access to multiple board rooms with A/V capability at no additional charge
C. Reduction in the cost of each meeting; and when catered by the Commons Café, support for non-profit organizations. Commons Café donates 100% of profits to charities.
D. Proximity to South Avenue medical practices, legislative offices and businesses

Third, membership increased by over 7% after residents attending the First Annual Medical Student, Resident and Fellows Dinner in May submitted their applications. We also engaged over twenty medical students who were interested in learning more.

Fourth, we have begun recent Comitia Minora meetings with educational sessions. These sessions included the aforementioned Community Based Organizations (CBOs) as well as award winning presentations from residents from each of the hospitals. Dr. Jack D'Angelo's discussion on the "Socratic Paradox" was the fourth and final presentation of the June meeting.

Fifth, the 2008 Bylaws update, completed by members of the Bylaws Committee in conjunction with advisors from MSSNY, was accepted by the Comitia Minora and will be submitted to the general membership for acceptance.

Sixth, the website was updated to facilitate easier navigation and access to Society related activity. Facebook has seen more traffic as events, photos and photos were posted.

Seventh, under the stewardship of our new President, Dr. Kokkinakis, we evaluated several law firms and chose the law firm of Weiss Zarett Brofman Sonnenklar and Levy.

During my tenure, I asked that the Society's members to partner with the Island's wonderful Community Based Organizations to provide expanded Patient-Centered Care and help address the many social determinants of care. We could then, as an Island-Wide Team, better deal with substance abuse, overdose deaths, mental health issues, food deserts and the stigma related to: ethnicity, language, poverty and sexual orientation. Remember, as physicians, most studies indicate that we can only impact 15-20% of healthcare outcomes. As Island-Wide Team members, we will have the opportunity to multiply our impact several-fold.

Included with this June issue are articles generously submitted by MLMIC, Weiss Zarett Brofman Sonnenklar and Levy as well as awarding winning abstracts from the resident presentations.

In parting, let me extend my thanks to our Sponsors, Linda, our executive director, the Executive Board, the RCMS leadership, the leadership of the four other counties, the MSSNY leadership, the members at large and most importantly to my family for their moral support and volunteerism.

May God Bless America.

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MLMIC UPDATE

Computer in Exam Rooms May Hinder Effective Communication

MARCH 14, 2018

Computers in patient exam rooms have become commonplace in healthcare, but they may be perceived by both physicians and patients as a barrier to effective communication. *MedPageToday* recently addressed the subject when it published a perspective in which a patient confesses jealousy toward the doctor's computer. The patient, Howard Wolinky, a *MedPageToday* contributing writer, states: "It's actually disturbing when you talk to an expert about big things impacting your well-being, and they're focused on a computer screen. I feel like screaming: 'Hey Doc, I'm over here!'"

Many patients agree with Wolinksy. A study conducted by researchers at MD Anderson Cancer Center examined patients' perception of computer use during office visits. The results revealed that patients perceived physicians who communicated directly with the patient, without the computer, as more compassionate, professional and as having better communication skills. Additionally, study participants indicated a preference for a "face to face" physician as their provider.

Although eliminating the use of computers in exam rooms may be difficult, there are alternatives including the use of a scribe, voice activated dictation or taking written notes that may be dictated or entered into the EHR after the visit. To facilitate the use of computers during patient encounters, MLMIC's Risk Management Department has developed strategies on how best to engage the patient while still using this technology during the visit.

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SUMMARY OF LAVERN'S LAW

Expansion of Medical Malpractice Statute of Limitations

WHAT cases are covered by the law:

- Lawsuits based on an alleged negligent failure to diagnose cancer or a malignant tumor, whether by act or omission

HOW does the law work:

- In cases alleging the negligent failure to diagnose cancer or a malignant tumor, the case must be brought within 2 ½ years of the **later** of:
  a. When the patient knows or reasonably should have known of the alleged negligent failure to diagnose and knows or reasonably should have known that such alleged negligent failure has caused injury, BUT the case must be brought within 7 years of the alleged negligent failure to diagnose; OR
  b. With instances where there is continuous treatment for such condition, the case must be brought within 2 ½ years from the date of last treatment, which could be beyond 7 years from the alleged negligent failure to diagnose.

WHEN did the law take effect:

- The law took effect on January 31, 2018 and applies to all acts or omissions involving a negligent failure to diagnose cancer or a malignant tumor that occurs on or after January 31, 2018.

DOES the law apply to acts or omissions involving alleged negligent failure to diagnose cancer or malignant tumor occurring BEFORE January 31, 2018:

- YES, it does apply to such acts or omissions in two distinct categories:
  a. If the alleged negligent failure to diagnose occurred within 2 ½ years before January 31, 2018 (i.e., the act or omission occurred on or after July 31, 2015), then the new discovery rule outlined in bullet point 2 applies, but only for an act, omission or failure occurring on or after July 31, 2015.
  b. If a case based on an alleged negligent failure to diagnose cancer or a malignant tumor was barred from being filed under the old rule for such cases within 10 months before January 31, 2018 (i.e., the case was barred from filing suit on or after March 31, 2017), then the case may be brought within 6 months after January 31, 2018 (i.e., by July 31, 2018).

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MLMIC UPDATE

Diederich Data: New York Has Highest Per Capita Medical Malpractice Payout

APRIL 10, 2018

According to this year's medical malpractice payout data from Diederich Healthcare, New York is among only three states with total medical malpractice payouts exceeding $300 million in 2017. In addition, its total payout of $617,973,000 earns it the distinction as the state with the highest per capita payout ($313) in the nation.

This isn't surprising. As Lawsuit Reform Alliance of New York notes, "New York ranked first in each of the last five years, except for 2016, when it was bumped down a spot by New Hampshire." Total payouts in the Northeast, says Diederich, were responsible for 41.95 percent of the U.S. total, illustrating just how far out of line the numbers are in states like New York.

Unfortunately, it's one of the reasons New York is an extremely challenging business and professional environment for healthcare providers. The stakes are very high, and providers need excellent protection. It's why MLMIC operates with the highest level of fiscal responsibility and with business practices that ensure strong backing for the liability coverage we offer our policyholders. (In contrast, when companies advance unsustainable pricing practices, the risks are great.)

In addition to offering policyholders this kind of security, MLMIC monitors – and when possible – works to improve the environment for healthcare providers. You can find information about some of these efforts in *The Albany Report*, which MLMIC publishes periodically with a concise, insiders' view of pending legislative, regulatory and political developments that have an impact on the New York State medical malpractice insurance marketplace.

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Mathew J. Levy is a Principal of the firm. Mr. Levy is nationally recognized as having extensive experience representing healthcare clients in transactional and regulatory matters. Mr. Levy has particular expertise in structuring and negotiating joint venture agreements, stock purchase agreements, asset sale agreements, shareholders agreements, partnership agreements, termination agreements, settlement agreements, employment contracts, managed care agreements and commercial leases. Among the areas in which he specializes are coordinating mergers and acquisitions, compliance programs, ambulatory surgery centers, establishment of diagnostic and treatment centers, HIPAA privacy regulations, fee-splitting issues, Stark law issues, fraud and abuse rules and regulations, investigations regarding Medicare/Medicaid, Blue Cross Blue Shield, Oxford, United, AmeriChoice and other third party payor audits.

Mr. Levy advises healthcare clients on the day-to-day business operations that have the attention of the FBI, Office of Inspector General, District Attorney's, the U.S. Attorney's Office, the Office of Professional Medical Conduct and the Office of Professional Discipline.

Professional Discipline • Governmental Investigations • Litigation and Arbitration • Contracts and Business Transactions • White Collar Crime
Regulatory Compliance • Practice Formation • Mergers and Acquisitions • Asset Protection and Estate Planning • Medical Financial Audits

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Risk Management Tips

Managing Patient Non-Compliance

The Risk:

Patient noncompliance is one of the most difficult challenges for healthcare providers. Noncompliance may include missed appointments and the failure to follow a plan of care, take medications as prescribed, or obtain recommended tests or consultations. The reasons given by patients for noncompliance vary from the denial that there is a health problem to the cost of treatment, the fear of the procedure or diagnosis, or not understanding the need for care. Physicians and other healthcare providers need to identify the reasons for noncompliance and document their efforts to resolve the underlying issues. Documentation of noncompliance helps to protect providers in the event of an untoward outcome and allegations of negligence in treating the patient.

Recommendations:

1. Establish an office policy to notify providers promptly of all missed and canceled appointments. We recommend that this be done on a daily basis.
2. Formalize a process for follow up with patients who have missed or cancelled appointments, tests, or procedures. This process should include recognition of the nature and severity of the patient's clinical condition to determine how vigorous follow up should be.
   a. Consider having the physician make a telephone call to the patient as a first step when the patient's condition is serious.
   b. If the patient's clinical condition is stable or uncomplicated, staff should call the patient to ascertain the reason for the missed or canceled appointment.
   c. All attempts to contact the patient must be documented in the medical record. d. If no response or compliance results, send a letter by certificate of mailing outlining the ramifications of continued noncompliance.
3. During patient visits, emphasize the importance of following the plan of care, taking medications as prescribed, and obtaining tests or consultations.
4. Seek the patient's input when establishing a plan of care and medication regimen. Socioeconomic factors may contribute to the patient's noncompliance.
5. To reinforce patient education, provide simple written instructions regarding the plan of care. Use the teach-back method to confirm that patients understand the information and instructions provided.
6. With the patient's permission, include family members when discussing the plan of care and subsequent patient education in order to reinforce the importance of compliance.
7. When there is continued noncompliance, patient discharge from the practice may be necessary. The attorneys at Fager Amsler Keller & Schoppmann, LLC are available to discuss patient noncompliance and the discharge of a patient.

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September 28, 2017

Via Email and Fedex

Sal Volpe, MD
Richmond County Medical Society
460 Brielle Avenue
Administrative Building, Room 202
Staten Island, New York 10314

Re: Proposal

Dear Dr. Winter:

First of all, I would like to take a moment to thank you, and the leadership of the Richmond County Medical Society for the honor of submitting a proposal to be your Counsel. It is our hope that through the ongoing privilege of serving as Counsel to your organization, we can continue to be of great benefit and assistance to you, your leadership, physicians and staff.

As Counsel to your organization, Weiss Zarett Brofman Sonnenklar & Levy, PC stands ready to meet your needs through experienced representation in each of the varied areas you seek assistance, counsel, and compliance.

As Counsel to your organization, Weiss Zarett Brofman Sonnenklar & Levy, PC will provide the following benefits to the Society:

- Attendance of a Principal at Board of Directors Meetings via web conference or telephone conference (and issuance of "Breaking Medical/Legal Issues" Reports) as needed or requested by the Board of Directors – Without Charge,
- Quarterly (or as needed) Consultations/Meetings with the Executive Director on Society Matters – Without Charge,
- Unlimited Telephone Access for the Executive Director or Designee to a Principal for Consultation on Society matters – Without Charge,
- Authorship of Medical – Legal Articles and/or Research Assistance for Society publications – Without Charge,

- First Twenty-Five (25) Hours of Legal Services on any Society Legal Dispute – Without Charge. Thereafter, the next Twenty-Five (25) Hours at a 10% Discount and All Hours in Excess of Fifty (50) at a 15% Discount.

In addition to the foregoing, Weiss Zarett Brofman Sonnenklar & Levy, PC can also provide your organization with expertise from a number of unique healthcare perspectives through its employment of experience healthcare professionals.

The Richmond County Medical Society agrees to prominently display Weiss Zarett Brofman Sonnenklar & Levy as its Counsel on its website; provide a booth at the annual convention free of charge.

Very truly yours,

Weiss Zarett Brofman Sonnenklar & Levy, PC

By: Mathew J. Levy /sbs
Mathew J. Levy

MJL/sbs

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