Health Law Developments

The Newsletter of the Health Law Section
State Bar of Georgia
Summer 2018

From the Chair

Dear Friends and Colleagues,

This Newsletter is chock full of the thought leadership you've come to expect from the Health Law Section. We are grateful to our wonderful authors and for the continuing leadership of Keri Conley and Rebecca Merrill, who have again devoted substantial time and talent to bring us a first-class publication.

We are honored to announce that the Health Law Section was selected this year to receive an Award of Achievement by the State Bar of Georgia. This Award reflects the hard work and dedication of our Executive Committee and many other members of our Section, as you can see from a review of Section events this year.

The first half of 2018 has been lively for our Section, and the best is yet to come!

In February, we announced the selection of three new members of our Executive Committee:

- Christy Jordan, General Counsel, Southeast Georgia Health System
- Wade Pearson Miller, Partner, Alston & Bird
- Beth Stephens, Senior Director, Georgia Watch

Please join me in welcoming Beth, Wade, and Christy to the EC. We are grateful for their service to the Section.

In March, the Section hosted 90 guests for a CLE lunch program moderated by our own Keri Conley and featuring Kelly Cleary (Deputy General Counsel, U.S. Department of Health & Human Services) and Blake Fulenwider (Deputy Commissioner, Chief of Medical Assistance Plans, Georgia Department of Community Health). Thank you, Keri, and many thanks also to Wade Miller and Alston & Bird for hosting this very successful event.

And how we do love to support our health law students! We covered the cost for several students to attend our CLE programs this year. In April, we also awarded Alan Rumph Memorial Scholarships to four outstanding health law students at GSU, Emory, Mercer, and UGA. Thanks to former Section Chairperson Mark Kashdan for coordinating these scholarships.

This spring, we launched an inaugural class of Health Law Fellows. Conceived by EC member Brian Stimson, the Health Law Fellows program supports Georgia law students accepting unpaid summer internships in health law positions with public interest organizations, government agencies, and nonprofits.

Through their internships, the students gain valuable health law experience and career opportunities. We hope the fellowship program will inspire health law students for many years to come.

For their role in bringing the new fellowship program to life, I would like to recognize our entire EC and give special thanks to Keri Conley, Amy Fouts, Rebecca Merrill, Lynnette Rhodes, Beth Stephens, and our law school partners: Professor Erin Fuse Brown (GSU), Stacie Kerschner (GSU), Professor Alex Scherr (UGA), Professor Elizabeth Weeks (UGA), Professor Leslie Wolf (GSU), and their colleagues who supported the launch of this fantastic program.

This year, we also recognized an opportunity to promote mentorship as a benefit for members of the Health Law Section. As you'll read elsewhere in the Newsletter, the EC approved a new Mentorship Program, and we are preparing to welcome our inaugural class of Mentors and Mentees in September.

SAVE THE DATE – The Advanced Health Law Seminar will take place on Friday, Oct. 12, 2018, at the Four Seasons Hotel in Atlanta. Planning for this popular, full-day CLE program is underway. We've hit "refresh" on our format this year, and we're excited to bring you the stellar content you expect, with a few new twists.

Like what you see? Please encourage your colleagues to join the Health Law Section. Our outstanding programs and activities offer something for everyone in health law.

Best regards,

Lynn M. Adam, Chairperson, Health Law Section

Inside This Issue

Past Health Law Section Chairs

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HHS' Latest Initiatives to Lower the Medicare Appeals Backlog:

Low Volume Appeals Settlement Option and the Expansion of the Settlement Conference Facilitation Program

By Lidia Niecko-Najjum and R. Ross Burris III[1]

Inefficiencies related to the Administrative Law Judge (ALJ) level Medicare appeal process of denied claims remain unresolved and, as a result, the number of appeals submitted is likely to continue to increase due to the nature of the Medicare Fee-For-Service Recovery Audit program.

Nonetheless, the Department of Health and Human Services (HHS) has recently proposed two initiatives to relieve this backlog: the new Low Volume Appeals (LVA) settlement option[1] and the expansion of the Settlement Conference Facilitation (SCF) program.[2] HHS aims for these initiatives to help address the ALJ level Medicare appeals backlog that has resulted in a nearly three-year adjudication process for each denied Medicare claim, estimated at 1,057 days by the Chief Judge Nancy Griswold as of Feb. 28, 2017.[3]

Described below are the LVA settlement option and the proposed expansion of the SCF program, as well as a few key points about each option for appellants to keep in mind.

LVA Settlement Option

The LVA settlement option is an administrative settlement process that has been offered by the Centers for Medicare and Medicaid Services (CMS) since Feb. 5, 2018, to providers and suppliers with fewer than 500 Medicare Part A and B claims pending as of November 3, 2017, combined, where no single claim appeal exceeds $9,000. These appeals will be settled at 62 percent of the net allowed amount. While this option was supposed to end in April of 2018, CMS extended it until June 8, 2018.

There are five key components of the LVA settlement option:

1. An eligible appellant submits an Expression of Interest (EOI) to settle eligible claims under the LVA settlement option to CMS on a form provided by CMS.[4]
2. CMS then confirms that the appellant is eligible for the LVA settlement option:
    - Eligible appellants include Fee-For-Service Medicare Part A and Part B providers, physicians, and Durable Medical Equipment suppliers with fewer than 500 appeals associated with their National Provider Identifiers (NPIs) pending before the Office of Medicare Hearings and Appeals (OMHA) and the Medicare Appeals Council (Council) at the Departmental Appeals Board, collectively.
3. Once an appellant is deemed eligible, then CMS determines whether each submitted appeal is eligible for the LVA settlement option:
    - Importantly, all of the appellant's eligible appeals must be settled—the appellant may not choose to settle some eligible appeals but not others.
    - An "eligible appeal" must meet the following elements:
        - The appeal was properly and timely filed at the OMHA or Council level as of Nov. 3, 2017.
        - The appeal has a total billed amount of $9,000 or less.
        - The claims included in the appeal were submitted for payment under Medicare Part A or Part B.
        - The claims included in the appeal were not part of an extrapolation.
        - The claims included in the appeal were fully denied by a Medicare contractor and remain in a fully denied status in the Medicare system.
        - The appeal must still be pending at the OMHA or Council level of review as of the date the LVA Settlement Agreement with CMS would be fully executed – if a decision is rendered on an appeal prior to execution of the Agreement, then the appeal is not eligible for settlement.
4. Once the appeal is determined eligible, CMS sends notification within 30 days of receiving the EOI, along with a spreadsheet of all potentially eligible claims and an LVA Settlement Administrative Agreement for appellant to sign.
    - Appellant must confirm that the claims are eligible and must validate the spreadsheet.
    - Within 15 business days of receipt, appellant must sign the LVA Settlement Agreement or send an Eligibility Determination Request (EDR) to dispute any appeals that are listed or missing within the same timeframe. CMS will respond in 30 days to an EDR. If appellant cannot take action within 15 business days, then appellant must communicate with CMS to determine an alternative submission timeline. Otherwise,

without a timely response to CMS, the appellant will be considered to have abandoned the LVA settlement option and will be removed from the process.

5. Once the Agreement is countersigned by CMS, the applicable Medicare Administrative Contractors (MACs) price the claims and send a lump payment to appellant within 180 days. The settled appeals are then dismissed.

Based on CMS's guidance, providers should keep the following in mind about the LVA settlement option:

1. CMS is willing to settle with as many appellants as possible, so CMS continues to encourage appellants to submit an EOI.
2. Submitting an EOI does not bind an appellant to a settlement—a provider may still decline the final proposed LVA Settlement Agreement.
3. Claims included in this settlement will continue to show as "denied" in the applicable CMS database—this may be a key issue for providers seeking secondary payments.
4. Settled claims will be excluded from future review by a MAC or Recovery Auditor but not Comprehensive Error Rate Testing (CERT) reviews or investigations related to potentially fraudulent claims. For dual eligible beneficiaries, the appellant must notify the state Medicaid agency when they receive payment from another payer.
5. The settlement amount is 62 percent of the net claim approved amount, not necessarily the amount billed, and the net amount is not disclosed before the Agreement is signed.
6. Any interest paid by the appellant after the claim was denied will be refunded, but no interest will be paid for the claim under appeal.

Expansion of Settlement Conference Facilitation (SCF) Program

The SCF is an alternative dispute resolution process for eligible claims pending appeal in front of an ALJ, and the expansion of the SCF program will be a separate and distinct initiative from the LVA settlement option. It will be offered by OMHA to providers and suppliers with greater than 500 Medicare Part A and B claims pending after November 3, 2017, or any number of appeals that exceed $9,000. There is no set percentage for which these appeals would be settled. OMHA is still implementing the SCF expansion internally and so this option is not yet available to appellants. However, OMHA has provided the following details about appellants' and claims' eligibilities.

1. Eligible appellants must be Medicare Part A and/or Part B providers or suppliers assigned an NPI, with a total of 500 or more appeals pending at OMHA and the Council combined; or with any number of appeals pending at OMHA and the Council that each has more than $9,000 in billed charges.
2. Eligible appeals are limited to the following:
    a. Request(s) for ALJ hearing or Council review after November 3, 2017.
        i. But appeals may not have been scheduled for an ALJ hearing and an ALJ hearing may not have been conducted.
    b. Request(s) for ALJ hearing that arise from a Medicare Part A or Part B Qualified Independent Contractor (QIC) reconsideration decision.
        iii. But requests may not arise from a QIC or ALJ dismissal order and may not involve services, drugs, or biologicals billed under unlisted, unspecified, unclassified, or miscellaneous healthcare codes (e.g., CPT Code 38999 Unlisted procedure, hemic or lymphatic system; K0108 Wheelchair component or accessory, not otherwise specified).
    c. Appeals arising from down coding of claims.
        i. But appeals may not involve payment disputes (e.g., the appellant was paid as billed, in full, by the contractor, but the appellant believes the fee schedule or contractor price amount is insufficient payment), and the beneficiary may not have been found liable for the amount in controversy after the initial determination or participated in the reconsideration.
    d. The amount of each individual claim must be $100,000 or less (for the purposes of an extrapolated statistical sample, the overpayment amount extrapolated from the universe of claims must be $100,000 or less).
        i. But appeals must not be involved in OMHA's Statistical Sampling Initiative.
3. Like with the LVA Settlement option, all pending OMHA and Council appeals associated with a single NPI and corresponding Provider Transaction Access Number (PTAN) must be included in the expanded SCF.

Based on CMS FAQs[5], potential appellants should keep in mind these fundamentals of the expanded SCF option:

- There will be no deadline to request SCF.
- Neither CMS nor the appellant is required to enter into a settlement agreement and both may reject offers of settlement from the other party.
- If a settlement is not reached, the appealed claims will remain in queue and return to the OMHA or Council docket for adjudication. On the other hand, settlement agreements are binding and cannot be appealed.
- Settled claims will remain denied in Medicare's systems, and new remittance notices will not be issued. This could cause future claims related to the

settled claims to be denied. CMS has stated that it is reviewing this problem.

- There are no set criteria for determining a settlement amount and there is no prescribed settlement percentage in the expanded SCF. It is rather a negotiation between parties that is facilitated through mediation by an employee of OMHA. This means that the parties may settle for 25% of the approved amount on the claims, for example.
- The expanded SCF is limited to appealed claims that have not yet been scheduled for an Administrative Law Judge hearing. Additionally, appeals are ineligible for expanded SCF if a hearing was already conducted.
- An expanded SCF conference will be conducted via telephone only.

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The new LVA settlement option and the expansion of the SCF program both have their potential advantages, as well as draw backs, for providers to consider. As such, consideration of possible participation in both programs should become part of providers' claim appeals strategies. Be sure to work with your health care attorneys and reimbursement professionals to determine if these programs are right for your provider.

Endnotes

1 CMS, Low Volume Appeals Initiative, *available at* https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/Low-Volume-Appeals-Initiative.html (last visited 5/4/2018).

2 HHS.gov, Settlement Conference Facilitation, *available at* https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/index.html (last visited 5/4/2018).

3 Office of Medicare Hearings and Appeals, Fiscal Year (FY) 2018 Congressional Justification, *available at* https://www.hhs.gov/sites/default/files/combined-office-of-medicare-hearings-and-appeals.pdf (last visited 5/4/2018).

4 CMS, Low Volume Appeals Settlement Expression of Interest, *available at* https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/LVA-External-Fillable-Expression-of-Interest.pdf (last visited 5/4/2018).

5 Settlement Conference Facilitation (SCF), SCF Expansion Frequently Asked Questions, *available at* https://www.hhs.gov/sites/default/files/scf-expansion-faqs%20remediated.pdf (last visited 5/4/2018).

New Summer Health Law Fellowship Program

The Health Law Section is pleased to announce the establishment of a new health law fellowship program. Four Georgia law students have been selected to receive the inaugural fellowship awards to support their work as unpaid summer interns in a health law position. To be selected, Health Law Fellows must demonstrate a commitment to pursuing a career in health law in Georgia and have an internship offer from an approved sponsor.

This year's Health Law Fellows, and the organizations where they will serve as interns, are as follows:

- Elizabeth Balte – Georgia State University College of Law, 2L, Atlanta Legal Aid, Health Law Division
- Michael Foo – Georgia State University College of Law, 1L, U.S. Department of Health & Human Services, Office of General Counsel
- Peter Nielson – Georgia State University College of Law, 2L, Office of the Mental Health Advocate, Georgia Public Defender Council, and the HeLP Legal Services Clinic
- Georgia Turner – University of Georgia School of Law, 1L, Children's Healthcare of Atlanta

We congratulate our Health Law Fellows on their awards and look forward to hearing about their internship experiences this summer!

Georgia Legislature Establishes Micro-hospital Concept

By Elizabeth Kitchens[1]

In recent years, micro-hospitals have begun cropping up across the country as an alternative to traditional hospitals and other health care settings. Acting on a recommendation of the House Rural Development Council, the General Assembly recently enacted legislation making certain changes to Georgia's Certificate of Need (CON) Act in an effort to ease the creation of micro-hospital's in the state. Only time will tell if "thinking small" is the next frontier in rural health care in Georgia.

The House Rural Development Council was created by House Resolution 389 during the 2017-18 Regular Session.[1] The Council, which is comprised of 15 members of the House of Representatives, is charged with engaging in an intensive, two-year study of the challenges facing Georgia's rural areas and making recommendations to address them, including potential legislative solutions.[2] Among the challenges being studied by the Council is rural areas' deficiency in access to health care.[3] This area of study comes as no surprise to those familiar with rural health care in Georgia. Since 2010, six rural hospitals in Georgia have closed their doors, and a 2016 study conducted on behalf of the National Rural Health Association suggested that more than half of the state's remaining rural hospitals are vulnerable to closure.[4,5]

After holding meetings across the state, the Council issued an initial report with its findings and recommendations at the end of 2017.[6] One of the Council's recommendations was that the General Assembly amend the CON Act to establish the concept of "micro-hospitals."[7] An emerging trend in the health care industry, micro-hospitals are smaller versions of a traditional hospital.[8] A micro-hospital, which by definition has a low number of inpatient beds, typically offers a broader range of services (including inpatient care) than an urgent care center or freestanding emergency department but treats a lower acuity patient than a traditional hospital and does not offer the same breadth of services.[9] Because micro-hospitals are often cheaper to operate than traditional hospitals, some people believe that they hold great promise for bridging the gap in access to health care services in under-served areas, like rural communities.[10]

The General Assembly enacted the CON Act in 1983 to ensure that health care services in Georgia are provided in a manner that avoids unnecessary duplication of services, that is cost effective, that provides quality health services, and that is compatible with the health care needs of the various areas and populations of the state.[11] Under the CON Act, a health care provider must apply for and obtain a CON from the Georgia Department of Community Health (DCH) before developing a "new institutional health service."[12] "A new institutional health service" is a term of art in the CON Act that is defined in the statute and DCH's administrative rules.[13] If a proposed activity is *not* a new institutional health service, the activity does not require a CON because it falls outside the scope of the CON Act. In addition, the CON Act does not reach certain new institutional health services under express statutory exemptions.[14]

In response to the House Rural Development Council's recommendation, the General Assembly passed House Bill 769 on March 29, 2018, and the Governor signed it into law on May 2, 2018.[15] House Bill 769 amends the definition of a "hospital" in the CON Act to expressly include "micro-hospitals."[16] A "micro-hospital" is defined as "a hospital in a rural county which has at least two and not more than seven inpatient beds and which provides emergency services seven days per week and 24 hours per day."[17] Thus, to qualify as a "micro-hospital," the hospital must: (1) be located in a rural county; (2) have between two and seven inpatient beds; and (3) provide round-the-clock emergency services.[18] The requirement that a micro-hospital have at least two inpatient beds is consistent with Georgia's licensure regulations for hospitals.[19] To be licensed as a hospital, a facility must operate at least two inpatient beds.[20]

Notably, House Bill 769 creates a new micro-hospital exemption to the CON Act.[21] The exemption excludes from CON review "[t]he purchase of a closing hospital or of a hospital that has been closed for no more than 12 months by a hospital in a contiguous county to repurpose the facility as a micro-hospital."[22] Thus, the micro-hospital exemption allows a hospital located in a rural county that is either closing or has closed in the preceding 12 months to be purchased by a hospital located in a contiguous county and repurposed as a micro-hospital without CON review and approval. Under DCH's administrative rules, a person may not undertake an exempt activity without first obtaining a letter of determination (sometimes called a DET) from DCH confirming that the proposed activity is exempt from the CON Act.[23] Accordingly, while no CON is required, before purchasing the rural hospital, the acquiring hospital must obtain a DET ruling from DCH confirming that the proposed acquisition falls within the scope of the exemption.[24]

From a practical standpoint, the micro-hospital exemption makes only modest changes to the CON Act. Because of pre-existing CON Act exemptions, a CON is not required to acquire a hospital unless the hospital being acquired is owned or operated by or on behalf of a county or hospital authority.[25] Even then, if the purchaser

is also a county or hospital authority, no CON is required.[26] The micro-hospital exemption modestly expands upon these pre-existing exemptions by permitting a closing or closed rural hospital owned or operated by or on behalf of a county or hospital authority to be acquired by a non-county/hospital authority hospital without a CON. Otherwise, the new micro-hospital provisions allow activities that were already permissible under the CON Act.

Federal Considerations

Beyond Georgia law, health care providers wishing to operate micro-hospitals in the state must consider federal law requirements. Last fall, the Centers for Medicare and Medicaid Services (CMS) issued guidance clarifying Medicare's definition of a "hospital."[27] Section 1861(e) of the Social Security Act defines a hospital as an institution, that among other requirements, is "primarily engaged" in providing services to inpatients.[28] Under the new guidance, CMS will determine whether a facility is a hospital based on an evaluation of the facility "in totality," taking into account such factors as the average daily census and the average length of stay.[29]

While CMS indicates that a hospital is not required to have a specific inpatient to outpatient ratio to be "primarily engaged" in providing services to inpatients, CMS states that having the capacity or potential capacity to provide inpatient care is not the equivalent of actually providing such care.[30] A patient is considered an inpatient for Medicare purposes if the patient is formally admitted by a physician who expects that the patient will remain admitted as an inpatient for at least two midnights (the Two-Midnight Rule).[31] Because of the Two-Midnight Rule, CMS indicates that an average length of stay of two midnights is one of the benchmarks for being a hospital.[32]

Additionally, under the new guidance, CMS will require state surveyors to determine whether or not a facility is in compliance with Medicare's hospital definition. Because a hospital is defined as an institution that is primarily engaged in providing services to "inpatients" plural, CMS will require that a facility have at least two inpatients at the time of the survey in order for the survey to be conducted.[33] If the facility has less than two inpatients, the surveyors will perform a review of the facility's admission data while onsite to determine if the facility has had an average daily census of at least two and an average length of stay of at least two midnights over the last 12 months.[34] If the facility meets these criteria, a second survey will be attempted at a later date.[35] If the facility does not, CMS instructs that the facility is "most likely not primarily engaged in providing care to inpatients," and thus not a hospital, and the CMS Regional Office should evaluate other factors to determine if a second survey should be attempted.[36]

Those factors include, but are not limited to:

- The number of provider-based off-campus emergency departments;
- The number of inpatient beds in relation to the size of the facility and services offered;
- The volume of outpatient surgical procedures compared to inpatient surgical procedures;
- Patterns and trends in the average daily census that suggest inpatients are regularly discharged before the week;
- Staffing patterns that support 24/7 inpatient care versus outpatient operations; and
- How the facility advertises itself to the community and whether it suggests that the facility does not consider itself as a hospital primarily engaged in providing inpatient services.[37]

The CMS guidance has important implications for any micro-hospitals established in Georgia. While Georgia's CON and licensure rules only require a micro-hospital to operate a minimum of two inpatient beds to be classified as a hospital, CMS has indicated that a facility approved as a hospital by a state still may not meet Medicare's definition of a hospital.[38] Further, it may be difficult for a micro-hospital with a small number of beds to meet Medicare's requirement of an average daily census and average length of stay of two or more. Providers should carefully study the factors that CMS will evaluate in determining whether a facility is a hospital and closely monitor the facility's admission data to ensure compliance.

Elizabeth Kitchens is a Partner in the Health Industry practice group at Parker, Hudson, Rainer & Dobbs, LLP.

1 H.R. 389, 154th Gen. Assemb., Reg. Sess. (Ga. 2017).
2 Id.
3 Id.
4 North Carolina Rural Health Research Program, Rural Hospital Closures: 83 Closures from January 2010-Present, http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
5 Lauren Webber & Andy Miller, "A Hospital Crisis is Killing Rural Communities. This State is Ground Zero," Georgia Health News (Sept. 22, 2017), http://www.georgiahealthnews.com/2017/09/hospital-crisis-killing-rural-communities-state-ground-zero/.
6 House of Representatives Rural Development Council Recommendations Overview (2017), http://www.house.ga.gov/Committees/en-US/HouseRuralDevelopmentCouncil.aspx.
7 Id., p. 9.
8 Virgil Dickson, "New Accreditation Approach Could Curtail Growth of Micro-Hospitals," Modern Healthcare (Dec. 16, 2017), http://www.modernhealthcare.com/article/20171216/NEWS/171219920.
9 Kalyn Saulsberry, "To Grow Your Hospital Think Micro," Advisory Board (May 20, 2016), https://www.advisory.com/research/financial-leadership-council/at-the-margins/2016/05/micro-hospitals.
10 Michelle Andrews, "Microhospitals May Help Deliver Care in Underserved Areas," NPR Health News, https://www.npr.org/sections/health-shots/2016/07/19/486500835/microhospitals-may-help-deliver-care-in-underserved-areas.
11 O.C.G.A. § 31-6-1.
12 O.C.G.A. § 31-6-40(a)-(b).
13 O.C.G.A. § 31-6-40(a)(1)-(7); Ga. Comp. R. & Regs. 111-2-2-.01(39).
14 O.C.G.A. § 31-6-47(a); Ga. Comp. R. & Regs. 111-2-2-.03.
15 H.B. 769, 154th Gen. Assemb., Reg. Sess. (Ga. 2018).
16 Id, § 4 (amending O.C.G.A. § 31-6-2(21)).
17 Id, § 4 (codified as O.C.G.A. § 31-6-2(23.1)).
18 The bill also amends the definition of a "rural county" in the CON

Act to include Georgia counties with a population of less than 50,000 residents, rather than 35,000 residents as was formally the case. Id. § 4 (amending O.C.G.A. § 31-6-2(32)).

19 Id. By definition a micro-hospital must provide round-the-clock emergency services. In the past, DCH has taken the position that an existing CON-authorized hospital is not required to continue to operate an emergency department. Accordingly, under pre-existing CON law, it is permissible to acquire an existing CON-authorized hospital with an emergency department and then cease providing emergency services at that facility.

20 O.C.G.A. 31-7-1(4)(A); Ga. Comp. R. Reg. 111-8-40-.02(f).

21 In addition, House Bill 769 amends the CON Act's relocation exemption to allow the relocation of a micro-hospital within the same county without CON review and approval. Id., § 5.

22 Id., § 5 (codified as O.C.G.A. § 31-6-47(9.2)). Under the CON Act's "12 Month Rule," if a health care facility, such as a hospital, fails to offer clinical health services on a regular basis for more than a 12 month period, the health care facility's CON authority to offer those clinical health services lapses. See O.C.G.A. 31-6-40(a)(5). Accordingly, if a hospital closed and ceased all hospital operations for more than a 12-month period, its CON would lapse.

23 Ga. Comp. R. & Regs. 111-2-2-.10(2).

24 See id. A person may oppose a determination request by filing a written objection with DCH within 30 days of the filing of the request. If DCH grants the request, the opposing party has a right to a fair hearing under the Georgia Administrative Procedure Act and judicial review of DCH's final agency decision. Ga. Comp. R. & Regs. 111-2-2-.10(6).

25 O.C.G.A.§ 31-6-47(a)(9).

26 O.C.G.A. § 31-6-47(a)(9.1).

27 Survey and Certification Memo 17-44 (Sept. 6, 2017; rev'd Oct. 27, 2017).

28 42 U.S.C. § 1395x(e).

29 Supra, endnote xxi.

30 Id.

31 Id.

32 Id. Under DCH's hospital licensure rules, an inpatient is a person admitted to a hospital for an intended length of stay of 24 hours or longer. Ga. Comp. R. & Regs. 111-2-2-.10(2).

33 The Joint Commission and DNV have also announced that they will not conduct surveys at hospitals without at least two active inpatients.

34 Supra, endnote xxi. For facilities that have multiple campuses operating under the same CMS Certification Number, CMS indicates that it will determine the average daily census based on the total inpatient census for all campuses. Id.

35 Id.

36 Id.

37 Id.

38 Id.

Health Law Developments is looking for authors of scholarly articles. If you have an article to submit, please contact Keri F. Conley at kconley@gha.org.

2018 Executive Committee

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Can Mindfulness Make You a Better, Happier Lawyer?

By Charity Scott

Are you stressed out? Overwhelmed with work? Feeling disconnected from clients or colleagues, or from family and friends? Sensing a loss of meaning in your practice? You are not alone: recent studies confirm a crisis in well-being among lawyers. This article discusses how mindfulness can help you to cope with the inevitable challenges of being a good lawyer and to find renewed health and happiness in your life.

Crisis in Professional Well-Being

"To be a good lawyer, one has to be a healthy lawyer. Sadly, our profession is falling short when it comes to well-being. . . . [R]esearch suggests that the current state of lawyers' health cannot support a profession dedicated to client service and dependent on the public trust."[1] So begins the recent report by the National Task Force on Lawyer Well-Being (the "Task Force"). The Task Force represents professional organizations both inside and outside of the American Bar Association.

Research shows high rates of mental and behavioral health problems among lawyers. For example, a 2016 study of over 12,000 lawyers reported incidence rates for the several conditions as follows: for depression, 28 percent; for stress, 23 percent; for anxiety, 19 percent; and for problematic drinking, 21 percent (up to 36 percent depending on the screening test used).[2] Attorneys who screened positive for problematic drinking were at significantly higher risk for depression, anxiety, and stress.[3] In a profession that embraces an "alcohol-based social culture,"[4] alcohol is the number-one substance abuse problem for attorneys, with abuse of prescription drugs in second place.[5] One substance-abuse recovery expert who works with lawyers said that the main problem used to be mostly alcohol abuse, "but now almost every attorney that comes in for treatment, even if they drink, they are using drugs, too – Xanax, Adderall, opiates, cocaine and crack."[6]

ABA Endorses Mindfulness Meditation

The Task Force report recommended numerous ways to improve the well-being of lawyers, judges, and law students. Among these recommendations is mindfulness meditation:

> *Mindfulness meditation is a practice that can enhance cognitive reframing (and thus resilience) by aiding our ability to monitor our thoughts and avoid becoming emotionally overwhelmed. . . . Research has found that mindfulness can reduce rumination, stress, depression, and anxiety. It also can enhance a host of competencies related to lawyer effectiveness, including increased focus and concentration, working memory, critical cognitive skills, reduced burnout, and ethical and rational decision-making. Evidence also suggests that mindfulness can enhance the sense of work-life balance by reducing workers' preoccupation with work.*[7] *[Citations omitted.]*

Can mindfulness really do all that? This article offers an introduction to mindfulness to answer that question and the one in the title of this article. [Sneak preview to the answers: Yes.]

What Is Mindfulness?

According to professor emeritus Jon Kabat-Zinn, the founder of the well-known, well-respected, and well-researched Mindfulness-Based Stress Reduction program, mindfulness is "awareness, cultivated by paying attention in a sustained and particular way: on purpose, in the present moment, and non-judgmentally."[8] Let's break down the phrases in this definition to see what they each mean.

Focusing Attention – Better Lawyering

What does it mean to pay attention "on purpose"? In our over-scheduled, on-demand, 24/7-connected, and social-media filled world, constant and chaotic distractions have become a major impediment to professional and personal satisfaction. One study found that mind-wandering is very common, occurring on average 47 percent of the time during the day.[9] That is a lot of time spent not thinking about what one is doing in the moment of doing it, whether working, writing, reading, talking with others, driving, eating, taking care of children, or whatever. To make matters worse, the study showed that people are less happy when their minds are wandering than when they are fully attentive to what they are doing, however mundane the activity.[10]

Research has shown that people who practice meditation can remain alert to distractions and return more easily to focused attention when they become aware that their mind has wandered.[11] One comprehensive review of mindfulness research concluded that the average meditator had stronger attention skills than 72 percent of non-meditators.[12] Related to improving attention control, mindfulness training has also been shown to improve working memory.[13] Bringing more focused attention and better working memory to your work can result in greater efficiency and productivity in your professional life, making you a better lawyer – as well as a more resilient one.[14]

Being Present – Happier Lawyering

What does it mean to pay attention "in the present moment"? Or another way to phrase the question, what is happening when the mind is wandering? When the mind is in its "default mode" (not attending to a task – i.e., when it is wandering or daydreaming), it is likely engaged in one or more of the following mental activities: self-referential processing (i.e., thinking about "I, me, and mine"); mental time travel (e.g., reminiscing, regretting, or ruminating about what happened in the past, or dreading, anticipating,

or fantasizing about what could happen in the future); and making judgments and social comparisons.[15]

All that mental activity of the mind in its "default mode" when we are not absorbed in a current task can be time-consuming, exhausting, stress-inducing, and unproductive if we are actually trying to get some work done. Mindfulness trains the mind to focus on the present, to notice when it has become distracted, and to gently return focus back to the present. In meditation, the object of focused attention is often the breath. The beginning meditator discovers how often and quickly her mind wanders (usually within seconds), and what a challenge it can be to notice that it has wandered and to return her focus to her experience in the present moment. And the mindfulness practice is to do it over and over again during each "sit" (as meditation practice is often called): as it becomes easier in meditation, it becomes easier in life.

Developing the ability to be fully present in the present moment experience can not only make you a better lawyer, it can also make you a happier lawyer. After all, the mind-wandering study above was titled *A Wandering Mind Is an Unhappy Mind*. Akin to its findings, well-being theory from the positive psychology field posits that engagement – being completely absorbed and engaged in the present task, whatever it may be – is one of the five key elements of personal well-being.[16]

Being present to whatever is happening in the here and now is also what helps to develop a balance between your work life and other important parts of your life: family, friends, recreation and hobbies, community service, spiritual activities -- wherever you find additional fulfillment and meaning in your life. Being fully present is what allows you to say, more often than you probably can do today, that "whatever happens at work, stays at work."

Suspending Judgment – Kinder Lawyering

What does it mean to pay attention "non-judgmentally"? And why would lawyers want to be less judgmental – isn't that what we are paid to be? To judge the merits of our client's case? To judge the weaknesses of the other side's? To deconstruct and then put together complex transactions and litigation? Would mindfulness take the edge off our ability to be successful, zealous advocates for our clients?

Fortunately, mindfulness will not make you less rational, analytical, organized, or hard-working or less energetic in representing your clients (if you have been following along, being less distracted and more present will likely make you a better lawyer). What paying attention non-judgmentally means is becoming less likely to act on your automatic *reactions* to whatever arises in the present moment and more likely to consider what your appropriate *responses* might be (e.g., those you will not later regret). Studies have shown that meditators are able to pay attention in a more open, non-reactive way.[17]

Like everyone else, lawyers have a cognitive negativity bias: humans react more strongly to negative stimuli than to positive ones.[18] This bias can be a good thing, for example, when we need to assess risks on behalf of clients or imagine worst-case scenarios in order to avoid them. Our negativity bias can be a harmful thing, however, when combined with our mind's natural tendency to make judgments about nearly everything -- people, places, experiences, things, etc. -- as good (pleasant), bad (unpleasant), or neutral.[19] This naturally judging and negative mindset can be amplified by a perfectionist streak common among lawyers, and it can be especially harmful when it is turned inward. It can also be harmful when we develop negative judgments about others and automatically act on them (however well-deserved we think those judgments or actions are).

We are simply hard-wired to make these kinds of judgments to identify perceived threats to ourselves and to sort things, situations, and people into "good" and "bad" categories.[20] While this hard-wired negativity and judgment-making may have served our ancestors well millennia ago when they needed to keep vigilant to scan the horizon for actual threats to their survival (from actual saber-tooth tigers), today it keeps us in constant hyper-alertness to our modern-day paper tigers: occupational and psychological stressors in the workplace and interpersonal relationships. Yet our minds and bodies minds experience today's threats and stressors as just as real and as life-threatening as an actual tiger's nearby growling. This chronic stress, driven by mental and psychological fears and perceptions, has led to the current crisis in the health and well-being of legal professionals.

Mindfulness is not about suppressing our active minds or jettisoning our negative thoughts and judgmental opinions (that would not be possible anyway). It is about developing a different relationship to them: becoming more aware that they are just thoughts, opinions, and judgments – and not reality. Through meditation – sitting quietly for a period of time trying to focus on one thing and watching how the mind automatically goes to thoughts, opinions, and judgments -- one learns how to befriend one's mind and remain non-reactive to its vicissitudes, meanderings, and ruminations. By becoming more aware and accepting over time of our own mind's internal workings, we can become kinder and more forgiving of ourselves. By accepting that others' minds work exactly the same way, we can become kinder and more forgiving of them. Mindfulness is about cultivating a discerning mind, rather than judging mind.[21]

Wellness and Health

There has been an explosion of scientific research on the effects of mindfulness meditation, literally thousands of articles. Happily, you do not have to read all of them to become acquainted with their conclusions and the benefits of mindfulness meditation, because Georgia Tech Professor Paul Verhaegen has already done so in a recent, readable volume. After carefully reviewing the scientific literature, he observed: "Mindfulness seems to have a positive impact on just about any psychological variable we (as a field) have looked at – it makes you less stressful, boosts your immune function, [and] makes you less anxious and depressed . . . ."[22] Since stress, anxiety, and depression were some of the health conditions among lawyers that most concerned the Task Force, this makes mindfulness a promising way to address them.

Wisdom – Professionalism and Ethics

So much scientific research has been on mindfulness meditation's potential to improve one's physical and mental health that it is easy to lose sight of its other, primary goals: to promote self-awareness and self-acceptance, foster compassion (for self and others), maintain open-mindedness and curiosity, enhance our ability to relish the here and now (however messy and chaotic), and see reality with clarity and equanimity.[23] Mindfulness thus can promote not simply wellness, but also wisdom. Many of these self-reflective traits and skills are foundational to making ethical decisions and reflecting the ideals of professionalism in law.

Judge Jeremy Fogel, Director of the Federal Judicial Center, has explored professionalism in the judicial context and how mindfulness could improve judicial demeanor and functioning. He has written that mindfulness could help judges to, for example, take a thoughtful approach to repetitive tasks, limit their unconscious assumptions, regulate their emotions in stressful situations, and strengthen their capacity for reflective thinking.[24] There is new scholarship calling for empirical research to study the potential for mindfulness training to improve ethical reasoning and behavior and reduce bias among legal professionals.[25]

Scientific evidence already supports that mindfulness meditation can enhance one's self-awareness and interpersonal relationships, which contribute to wise decisions and actions. Verhaegen found that research shows that mindfulness: ". . . dampens your negative emotions, amplifies your positive emotions, helps regulate your emotions, makes you less ruminative, takes the edges off negative personality traits, makes you more mindful, strengthens your self-concept, and makes you more empathetic and compassionate."[26]

The wellness effects of mindfulness meditation that probably most people are interested in -- stress reduction and mental health improvements – "are easily acquired and maintained: Just sit!"[27] Wisdom will take somewhat longer. Certainly mindfulness is not a cure-all for everything that ails the legal profession. Yet if the research shows that it "makes a person a little bit of a better human being, a little happier, a tad less rough around the edges, and just a bit more pleasant to be around,"[28] it is certainly worth giving it a try. For most meditators, the proof is in the pudding: undertaking the actual practice of meditation and discovering its beneficial effects for oneself, personally and directly.

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Endnotes

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Health Law Section Lunch, March 9!

The Health Law Section was pleased to present distinguished speakers from CMS and DCH at the March 9th event. The event was well attended and the discussion vibrant and informative. We appreciate all who attended.

Our special thanks to:

- Kelly Cleary, Deputy General Counsel, U.S. Department of Health & Human Services, and Chief Legal Officer, Centers for Medicare & Medicaid Services, Speaker
- Blake Fulenwider, Deputy Commissioner, Chief of Medical Assistance Plans, Georgia Department of Community Health, Speaker
- Keri Conley, Vice President of Legal Services for Georgia Hospital Association, Moderator
- Lynnette Rhodes, Brian Stimson and Lynn Adam for planning the meeting
- Alston & Bird for graciously hosting us in their Atlanta Office

(L) - Lynn Adam, introduces the panel.

(C) - Panelists Kelly Cleary (L) and Blake Fulenwider (C) with moderator Keri Conley (R).

(R) - A packed house listens to the various state and federal Medicaid initiatives.

New Section Mentorship Program

By Lynn M. Adam, Chairperson, Health Law Section

The Section has approved a new Mentorship Program as an exclusive benefit for Section members.

Among many important objectives, the Program will serve as a "Welcome" to Section members with less than five years experience in health law (Mentees) and will assist them in navigating their careers. For a one-year term, they will be paired with experienced healthcare attorneys (Mentors) willing to share their wisdom, guidance, and encouragement. Mentors must have at least 10 years experience in health law.

We are grateful these experienced attorneys who responded to our call for Mentors in July. This Program would not succeed without you!

Each Mentor and Mentee will meet together monthly for one year. Starting in September, the class will attend an orientation and several group networking events. Group events are sponsored by the Section, and attendance is free. Mentees are asked to devote five hours to a pro bono service project or a Health Law Section activity during their participation in the Program.

Our aim is to promote collegiality, build bridges, extend networks, foster professionalism, and encourage the expansion of our health law bar.

We hope the Mentorship Program will serve the Section for years to come. Participation is encouraged for attorneys of all ages, ethnicities, genders and orientations, and with all types of health law practice – private practice, in-house, government, public interest, and others – throughout Georgia.

The Section is indebted to our Advisory Committee who earlier this year developed the guiding principles that helped us launch the new Program: Aaron Danzig, Amy Fouts, Lynnette Rhodes, Rebecca Merrill, Charlene McGinty, Charity Scott, and Scott Grubman. You rock.

We also owe a round of applause to our newly formed standing Advisory Board. The Board will oversee the inaugural class of Mentors and Mentees for the coming year. Please extend a word of thanks to the following Board members for their outstanding service to the Section: Aaron Danzig, Amy Fouts, Lauren Gennett, Brittany Jones, Keith Mauriello, Charlene McGinty, Wade Miller, Jay Mitchell, Dan Mohan, Lynnette Rhodes, Barb Rogers, Charity Scott, Sean Sullivan, and Terriea Williams. It's going to be a great year!

There's No Such Thing as a Free Lunch. Tips to Avoid Paying the Price for Industry-Sponsored Meals

By Amanda Helton

Drug and device manufacturer sponsored meals are a longstanding tradition in the health care industry and are viewed by some as a traditional pathway for communication between physicians and vendors, aiding the sharing of information and enhancing innovation in health care. On the other hand, recent studies demonstrate that these relationships may, in part, be based on impure motives with the potential for a negative impact on patients, providers, and the payer community alike. An article co-authored by a former drug representative describes common industry marketing techniques that vendors use to take advantage of physician vulnerabilities in order to influence their prescribing patterns.[1] The article reads, "Physicians are susceptible to corporate influence because they are overworked, overwhelmed with information and paperwork, and feel underappreciated. Cheerful and charming, bearing food and gifts, drug reps provide respite and sympathy."[2] Though many physicians are not aware of it or don't believe that a simple meal could influence their clinical practice, it is clear that pharmaceutical companies specifically target physicians on a routine basis in order to influence prescribing practices. In fact, the studies described below indicate that even limited acceptance of gifts from vendors can unduly influence prescribing practices.

Is the way to a physician's heart through their stomach?

The correlation between vendor meals and physician prescribing practices has been studied using various approaches and consistently the research has pointed to a strong association between the receipt of even one meal and the increased prescribing of the relevant drug. A frequently cited study published in *JAMA Internal Medicine* investigated 2013 data from the Open Payments program and physician prescribing data to Medicare patients, revealed a significant association between receipt of industry-sponsored meals and an increased rate of prescribing of promoted brand-name pharmaceuticals.[3] The study evaluated 279,699 physicians who wrote Medicare prescriptions in one of four drug classes.[4] The majority of physicians included in the study received a single meal with a value between $12 and $18. The study further indicated that receipt of more meals or meals costing more than $20 resulted in an even higher corresponding increase brand-named prescribing.[5]

Another study by ProPublica analyzed Open Payments data for 2014 and compared it with Medicare Part D data.[6] The study similarly concluded that, in general, physicians who receive gifts from vendors "prescribed a higher percentage of brand-named drugs overall than doctors who didn't," even when the gift was just a meal.[4] The study further indicated that physicians who received gifts or compensation of higher value from vendors also prescribed brand-named drugs at higher rates.[7] In 2014, the category of items most frequently gifted from vendors to physicians was food and beverage for a total of $224.5 million.[8]

Applicable Laws and Regulations

In many industries it is not an uncommon practice for vendors to drop off food and beverage at the office or pay for a meal with the targeted client; however, in the health care arena lawmakers have recognized the increased risk to patients associated with financial incentives provided to physicians by vendors.

PhRMA Code

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code sets industry expectations for interactions between pharmaceutical company representatives and health care professionals and delineates when vendor gifts are acceptable. More specifically, Section 2 of the Code addresses meals provided during informational presentations by pharmaceutical company representatives.[9]

According to the Code, meals are appropriate on an occasional basis as a courtesy when a vendor takes time during the day to speak with physicians and staff members. Any food and beverage should be accompanied by a presentation from the representative with content of scientific or educational value.[10] Furthermore, the meals should be modest according to local standards, not be provided in tandem with entertainment or a recreational event, and should be provided consistent with an informational communication.[11] While the Code offers some leniency for meals provided as part of a legitimate discussion, it also sets clear boundaries for other programs of dubious value. For example "dine & dash programs" are not appropriate under any circumstances, and even legitimate discussions should not include the healthcare professional's spouse or other guest.[12]

The Physician Payment Sunshine Act

The Physician Payments Sunshine Act requires drug and medical-device manufacturers to report to CMS every 'transfer of value' of $10 or greater to physicians and teaching hospitals in order to track and publicly disclose benefits such as free lunches provided by vendors.[13] The

purpose of the Sunshine Act is to provide transparency for these transaction, though it does not prohibit them. In 2014, CMS began tracking gifts to physicians from drug and device manufacturers on the Open Payments Database which is accessible for the public to view and search for industry payments to specific physicians and teaching hospitals.[2, 14] Although reporting to the Open Payments database does not by itself indicate wrongdoing or illegal conduct by the engaged parties, reporting does not mitigate, and perhaps even enhances, the risk of potential liability based on other relevant laws, like the Federal Anti-Kickback Statute, False Claims Act, and Civil Monetary Penalties laws.

Anti-Kickback Statute, False Claims Act, and Civil Monetary Penalties Law

The Anti-Kickback Statute (AKS) prohibits payments, whether direct or indirect and in any form, made with the intent to induce or reward "referral or generation of federal healthcare business."[15] The statute covers anyone who offers, pays, solicits, or receives any unlawful remuneration.

Vendors providing food and beverage to healthcare professionals may be construed by the government as a violation of AKS "if any one purpose of the gift or marketing promotion is to induce the healthcare professional to refer patients for items or services or in return for recommending purchasing or ordering any item or service payable under a federal healthcare program."[16] Regardless of any legitimate reason for providing these benefits, any illegal intent is sufficient to establish a violation the AKS.[17]

The statute extends equally to the solicitation or acceptance of remuneration for referrals.[18] Therefore, the vendor providing food and beverage, as well as the recipients may be held liable under AKS, again if any one purpose is intent to induce referral of patients for items or services or as a reward for such behavior.[19] As of 2016, civil penalties for violating the AKS may include penalties of up to $73,588 per kickback plus treble damages. Criminal penalties for violating the AKS may include fines, imprisonment, or both.[20] Recently the Department of Justice disclosed a settlement of $3.1 million in Massachusetts regarding violations of the False Claims Act with Abiomed, Inc. for the purchase of "lavish meals" for physicians to induce the purchase of Impella heart pumps costing more than $20,000 each.[21] In 2016 a criminal complaint filed in New Jersey, based on conspiracy to violate the Anti-kickback Statute resulted in a three-year deferred prosecution agreement where Olympus Corp. of the Americas agreed that agents of the corporation had induced physicians and hospitals to do business with the company by providing kickbacks including lavish meals, among other extravagant perks.[22]

In addition to civil and criminal punishment for violating the AKB, the False Claims Act (FCA) provides for further civil liability for any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the Federal Government.[23] Civil Monetary Penalties for violating the FCA may include fines of up to three times the amount of damages sustained by the Government as a result of the false claims plus up to $21,563 (in 2016) per false claim filed.[24] Furthermore, vendors, providers, and individuals billing federal healthcare programs can be excluded from participation as a result of these types of violations.[25]

State Law

In 2017, an amendment to Maine's Pharmacy Practice Act codified a prohibition on cash gifts and any gift given for the purpose of reciprocity to practitioners from manufacturers.[26] The law does allow for some gifts, particularly vendor provided food and beverage.[27] Vendors are permitted to provide modest refreshments to practitioners in connection with meetings or presentations occurring "in a venue and manner conducive to informational communication and address the benefits, risks and appropriate uses of prescription drugs or medical devices; disease states; or other scientific information."[28]

A more recent change to New Jersey law expresses the desire of state regulators to hold parties to a higher standard of responsibility for vendor-physician transactions. In December 2017, New Jersey's Attorney General finalized a new set of rules governing physician interactions with pharmaceutical companies titled *Limitations on and Obligations Associated with Prescriber Acceptance of Compensation from Pharmaceutical Manufacturers*.[29] Effective January 2018, among other provisions regarding contracting between New Jersey physicians and vendors, the final rule provides that physicians are subject to a $15 dollar cap for meals related to all activities.[30] This rule is unique in that, rather than applying to pharmaceutical manufacturers, it imposes provider liability by tying compliance with the rule to physician licensure as opposed to the PhRMA Code, which holds the vendor responsible for industry set standards for reasonable interactions between vendors and healthcare professionals.[31]

Tailoring Policy to Fit Culture

Organizations should consider the inherent conflict of interest associated with vendor-physician relationships and should provide guidance through internal policy for these interactions. Some organizations such as Yale, UNC Health Care System, and the hospital of the University of Pennsylvania to name a few, have entirely banned healthcare professionals from accepting meals from vendors.[32] Advocates for an outright ban on vendor gifts argue a ban for the sake of simplicity. A total ban is unambiguous and removes the inherent difficulty in complying with a policy that conditionally allows vendors gifts, thus freeing healthcare professionals from the burden of deciding whether a gift is appropriate.[33] Another reason to ban vendor provided food and beverage altogether is that it eliminates the administrative load on the organization to monitor and track each transaction and verify that associated healthcare professionals are following the policy. While a total ban might be prudent stewardship when it comes to administering a policy, many

healthcare professionals have participated in the long-time tradition of vendor provided meals and consider these treats a job-related perk.

While banning all vendor gifts may be the most cautious approach, doing so all at once may be difficult. A moderate approach leading to change over time may be a more practical. Physicians have differing opinions as to the level of influence vendor provided meals have on their prescribing patterns. For example, on commentator stated that some physicians "voice concerns about the influence on prescribing behaviors of small gifts, meals, and CME events sponsored by drug companies, while other physicians believe and feel indignation about the suggestion that a free meal could possibly influence their professional behavior after years of intensive study and the rigors of medical practice."[34] When advocating for change in your organization's vendor-provided meals policy, encourage physicians to look at their record on the Open Payments Database for two reasons: 1) to verify that the information provided by vendors is correct, and 2) to promote overall awareness of how the vendor gifts they receive could be construed in the court of public opinion. Introducing change in an organization's culture, particularly with a topic that people are passionate about such as food, a middle of the road approach might provide for a more palatable transition.

Before implementing a change in policy, it may be wise to consider the varying degrees of attachment to vendor provided meals that your organization's healthcare professionals may have; therefore, it is important to consider the traditions and culture of the organization throughout the process of developing a vendor-meals policy. The PhRMA Code can serve as guidance for developing a moderate stance on vendor meals while still providing adequate protection for healthcare providers, increasing awareness regarding the ethical and legal issues associated with vendor provided meals and helping to alleviate culture shock. In order to comply with relevant federal laws and minimize the impact of potential conflicts of interest, the PhRMA Code allows meals as long as they are modest in value, occur in the context of providing scientific or educational information, and are provided in a venue that is conducive to the informational exchange.[35]

Amanda Helton is a Compliance Specialist at Northeast Georgia Health System in Gainesville.

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Final Four -

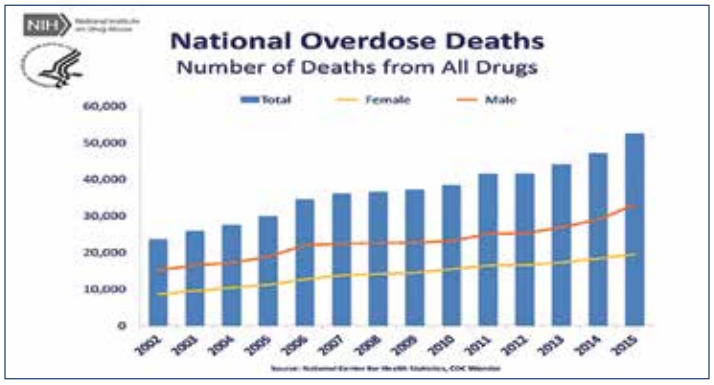
DOJ Versus Opioid Drug Manufacturers, Physicians & Pharmacist

By Daniel R. Crumby, JD, MBA, MHA, CHC

Recently, the Department of Justice created a new initiative to address the rapidly increasing volume of litigation against opioid drug manufacturers, providers, and pharmacists; the **P**rescription **I**nterdiction and **L**itigation (PIL) Task Force.

In the United States, 40 percent of all opioid overdose deaths involve prescription opioids and, in 2016, more than 46 people died every day from overdoses involving prescription opioids.[1] "Opioids were involved in 42,249 deaths in 2016, and opioid overdose deaths were five times higher in 2016 than 1999. In 2016, the five states with the highest rates of death due to drug overdose were West Virginia (52.0 per 100,000), Ohio (39.1 per 100,000), New Hampshire (39.0 per 100,000), Pennsylvania (37.9 per 100,000) and (Kentucky (33.5 per 100,000)."[2] According to the National Institute of Health's National Institute on Drug Abuse, there has been a steep incline in the number of overdose deaths from 2002 to 2015, as captured in Fig. 1 below.

Fig. 1:



The Department of Justice has already filed a Statement of Interest in one opioid and drug manufacturing lawsuit. That statement argues that the cost of treating and fighting the opioid crisis falls on the federal government, which administers Medicare prescription drug plans. Currently, the PIL Task Force is looking at existing state and government lawsuits against drug manufacturers to determine what assistance the Department of Justice can provide. In addition to potential criminal charges for the unlawful manufacturing, dispersing, dispensing, and possessing with the intent to manufacture, disperse, or dispense opioid drugs, drug manufacturers could potentially be charged and/or fined for multiple offenses, including the introduction of misbranded opioid drugs into commerce and using false, deceptive, and unfair claims to market opioid drugs.[3]

However, nothing prevents the Department of Justice or its United States Attorneys from pursing pharmacists and medical providers who illegally administer and prescribe opioid drugs. The federal government is armed with additional tools to help combat illegal opioid drug activity, including the criminal False Claims Act, the Anti-Kickback Statute, and the civil False Claims Act, among others.[4]

In addition to subjecting drug manufacturers, pharmacists, and medical providers--as business entities and individually--to possible criminal convictions, the federal government has previously used the above statutes to disgorge profits, administer civil and administrative penalties, strip away professional state licensure, and ultimately hand down the corporate and individual health care death sentence: exclusion from participation in Medicare, federally funded health care programs, and state health care programs.[5]

Drug Manufacturers have previously experienced this level of scrutiny from the Department of Justice regarding the unlawful marketing of the drug Bextra in early 2009; Rapamune in 2013; Vioxx; and more recently – Juxtapid.[6] Moreover, drug manufacturers have also been subject to federal scrutiny involving the False Claims Act and the Anti-Kick Statute.[7] In terms of pharmacists, United States Attorneys have prosecuted numerous pharmacists for health care fraud related to fraudulent billing; unlawful distribution of controlled substances; kickbacks, introducing misbranded drugs into interstate commerce, and money laundering. Finally, medical providers certainly have not been immune from the ire of justice in regards to prescribing opioids without a medical need.[8]

Even with all of these past criminal convictions and civil monetary penalties, the opioid crisis and the creation of the PIL Task Force presents new challenges as the number of opioid related deaths broadly impacts the United States and federal taxpayers. Moreover, the federal government has proposed investing billions of dollars to combat the

opioid crisis, the Drug Enforcement Agency conducted a "surge" of special agents and analysts to determine which pharmacists and prescribers were disproportionately prescribing opioid drugs, and the Federal Bureau of Investigation (FBI) and other federal agencies have brought together their assets and doubled the FBI's resources for targeting and disrupting online drug trafficking.[9]

The above interventions are some of the examples that the federal government is using to combat the opioid crisis and target opioid drug manufacturers, pharmacists, and medical providers–with almost limitless resources. This time, the federal government is coming with a full-court press and the Attorney General has vowed to use every civil and criminal tool at his disposal to pursue charges. In the near future, it would not be surprising if the Department of Justice--in coordination with the Department of Health and Human Services--created PIL Teams and assigned prosecutors, civil litigators, auditors, evaluators and other staff around the country to intervene and prosecute opioid related offenses. The function of those teams could be similar to the Health Care Fraud Prevention & Enforcement Action Teams which have been highly effective in restoring billions to federally funded healthcare programs.[10]

At Hall Booth Smith, PC, we continue to believe the best way for drug manufacturers, pharmacists, physicians and other healthcare providers to defend themselves against Opioid-related litigation is a strong offense, thorough compliance programs to detect and prevent health care fraud and diligent use of available Prescription Drug Monitoring Programs to avoid litigation in the first place. Moreover, we have a team of former federal and state prosecutors on staff dedicated to working with drug manufacturers, pharmacists, and healthcare providers to ensure compliance with opioid prescription best practices.

Daniel Crumby was a federal prosecutor in the Southern District of Georgia and the Western District of Texas and he represented the United States as a federal civil litigator. He focuses his practice on federal investigations, health care fraud and abuse, medical malpractice and long-term care.

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