THE CASE AGAINST IMPORTED DRUGS

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FEATURES

18 The Case Against Imported Drugs and Medical Devices
Physicians face significant liability for purchasing foreign prescription drugs and medical devices, even if done unwittingly. Here’s what you need to know to protect yourself. By Clay Countryman, Esq.

22 Safety in Numbers
The threat of health insurers getting even larger, the shift to value-based care and a government performance measure initiative are triggering an unprecedented wave of consolidation among physician practices. By Bruce Japsen.

PRESIDENT'S MESSAGE
2 If You’re Not Part of the Solution...
By Kathy M. Tynus, MD

PRACTICE MANAGEMENT
4 Heavy Fines for HIPAA Failures; Is Your Practice Ready?; Time to Get Fit!; Techniques to Manage Stress and Prevent Burnout; Credentialing Made Simple

PUBLIC HEALTH
8 Meningitis in Chicago; Flu Preparedness; Toxic Danger for Kids; A Step in the Right Direction

LEGAL
12 Understanding Your Fair Market Value

14 Compounding the Problem

16 Due Process for Doctors

MEMBER BENEFITS
26 An Open Invitation

30 Calendar of Events

31 New Members

31 Classifieds

WHO’S WHO
32 UIC’s New Health Affairs Chief
Robert A. Barish, MD, MBA, couldn’t be happier about his move on Jan. 1 into the role of vice chancellor for health affairs at the University of Illinois at Chicago. Unlike his predecessors, Dr. Barish not only oversees patient care, but also academic and research enterprises—a big job but one he’s been preparing all his career to do.
MESSAGE FROM THE PRESIDENT

If You’re Not Part of the Solution...

READERS of this column are familiar with the odyssey upon which we’ve traveled to address the problem of narrowing networks. We’ve met with patients, insurance company executives, the Illinois State Attorney General, and local specialty societies. We came away with the realization that what is happening with these insurance products is perfectly legal, which underscores the fact that rules and oversight are sorely lacking. The American Medical Association and even Medicare and the National Association of Insurance Commissioners have been clamoring for clarification of what constitutes an “adequate network.”

Last month a new bill was introduced in the Illinois House, HB 6562, which seeks to address this problem. This bill came about because of an effort by your Chicago Medical Society that in turn was taken up enthusiastically by the Illinois State Medical Society. ISMS drafted the bill and now our lobbyists are working furiously to garner support. Our bill achieved bipartisan sponsorship. If passed, it would be the most comprehensive legislation in the country to protect patients’ access to the care they need.

I first became involved in organized medicine after practicing as an internist for a few years and noticing some policies that were just not right. I would commiserate with colleagues who had similar complaints, and we’d wonder, “How did things get like this? Why isn’t anybody doing anything about it?” That’s when my colleague and mentor, Dr. Sharad Khandelwal, told me, “Kathy, you should join the Chicago Medical Society. That’s where you can do something about it.” I thought, “Why not? Can’t hurt, maybe they are working on it.”

Well, we’re working on it, I’m proud to say. And it’s a group effort that can’t happen without the support and participation of members like you. But we also need more members, not just to pay for programs and staff, but as a show of strength. I know that there are many cynical and disaffected docs out there who shake their heads and wonder, “How did things get like this? Why isn’t anybody doing anything about it?” Well, the solution has been right here all along, but it takes some commitment. We may not always agree on policy, but the only way we’ll even have a seat at the table along with insurers, pharmaceutical companies, the government, lawyers, etc., is to work together as one body. Not just for our specialty’s interest, but for the sake of all physicians and our patients. Silence is assent, and doing nothing means that others will make decisions for you and your patients.

I ask you all to call or email your Illinois legislators and ask for their support of HB 6562. I also ask you to share this with your friends and colleagues for their support and membership. Because, as the saying goes, “If you’re not part of the solution, you’re part of the problem.”

Kathy M. Tynus, MD
President, Chicago Medical Society
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Heavy Fines for HIPAA Failures

Physician practice and hospital pay $750,000 and $1.5 million

By Clay J. Countryman, Esq.

The Office for Civil Rights (OCR) recently announced two separate settlements with a hospital and a physician practice that highlight the importance of having HIPAA business associate agreements. Each of these HIPAA settlements was based on the organization’s failure to have a HIPAA business associate agreement in place with a third party with whom the organization had disclosed patients’ healthcare information. In each case, the third party recipients of the information committed or contributed to a breach under the HIPAA Privacy Rule.

On March 16, the OCR announced that North Memorial Health Care of Minnesota agreed to pay $1,550,000 to settle allegations that it violated the HIPAA Privacy and Security Rules by failing to enter into business associate agreement with a major contractor and failing to conduct an accurate and thorough security risk assessment. The OCR initiated an investigation of North Memorial following receipt of a breach report that an unencrypted, password-protected laptop was stolen from the locked vehicle of an employee of a business associate, Accreative, thereby impacting the electronic protected health information (ePHI) of 9,497 individuals.

The OCR discovered that North Memorial did not have a business associate agreement in place with Accreative. North Memorial had given Accreative access to North Memorial’s hospital database, which stored the ePHI of 289,904 patients. Accreative also received access to non-electronic protected health information (PHI) as it performed services on site at North Memorial.

The OCR commented that North Memorial failed to conduct a thorough risk assessment that incorporated all of its information technology equipment, including all applications, software, databases, servers, work stations, mobile devices and electronic media, network administration and security devices and associated business processes, applications, and data systems using ePHI.

Then on April 19, the OCR announced that Raleigh Orthopaedic Clinic, P.A. of North Carolina had agreed to settle charges that it potentially violated the HIPAA Privacy and Security Rules by failing to execute a business associate agreement prior to turning over PHI of approximately 17,300 patients to a potential business partner without first executing a business associate agreement. Under the HIPAA settlement with OCR, Raleigh Orthopaedic Clinic agreed to pay $750,000 and implement an extensive corrective action plan.

The OCR initiated its investigation of Raleigh Orthopaedics following receipt of a breach report on April 30, 2013. The OCR’s investigation indicated that Raleigh Orthopaedics released the x-ray films and related PHI of 17,300 patients to an entity that promised to transfer the images to electronic media in exchange for harvesting the silver from the x-ray films. The OCR discovered that Raleigh Orthopedic failed to execute a business associate agreement with this entity prior to turning over the x-rays and PHI.

In addition to the $750,000 payment, Raleigh Orthopaedics is required to revise its policies and procedures to establish a process for assessing whether entities are business associates; designate a responsible individual to ensure business associate agreements are in place prior to disclosing PHI to a business associate; create a standard template business associate agreement; establish a standard process for maintaining documentation of business associate agreements for at least six years beyond the date of termination of the relationship; and limit disclosures of PHI to any business associate to the minimum necessary to accomplish the purpose for which the business associate was hired.

OCR HIPAA Audits

Recently, the OCR updated the audit protocol that will be used to assess HIPAA covered entities’ and business associate’s compliance with the HIPAA privacy, security, and breach notification rules. The OCR also released a template that covered entities and business associates may use to keep track of their relationships. The release of the updated audit protocol and Business Associate tracking template is part of the implementation of the Phase 2 HIPAA Compliance Audits by the OCR.

The OCR sample business associate tracker contains a list of the specific information the OCR will request from a covered entity or business associate as part of the Phase 2 HIPAA Compliance Audits. In response to a request from the OCR, covered entities and business associates should be able to quickly produce the name of the business associate, type of service provided, contact information for two points of contact of the business associate, and the website URL for the business associate.

Based on the above recent settlements and other enforcement initiatives, physician practices should consider conducting a risk assessment using the new audit protocol to identify compliance issues and gaps in their documentation. Physician practices should also consider adopting an internal business associate tracking system that contains information that the OCR will request in an audit.
Is Your Practice Ready?

Phase Two of the 2016 HIPAA Audit Program is already under way  

By Cathryn Johnson

The HIPAA Audit Program under the Office for Civil Rights (OCR) is expanding and changing. Is your practice ready? If not, it’s time to get started. Providers will be audited to determine compliance rates with the HIPAA privacy, security, and breach notification rules.

The Current Status

Phase Two of the audit program is currently underway. OCR is currently obtaining and verifying contact information to identify covered entities and business associates for its audit pool. Communications from OCR are sent to covered entities by email. OCR expects providers to check their junk or spam email folders since emails from OCR may be incorrectly classified as spam.

Who: Every covered entity and business associate is eligible for an audit. The audit pool includes individual and organizational providers of health services; health plans of all sizes and function; and healthcare clearinghouses, EMR vendors, healthcare consultants, etc.

How: Once contact information is obtained, a questionnaire designed to gather data about the size, type, and operations of potential auditees is sent to covered entities and business associates. This data will be used to identify audit pools; auditees are chosen through random sampling techniques. If a covered entity or business associate fails to respond to the information requests, OCR will use publically available data to create or add to its audit pool.

Audit Process: OCR will conduct desk and on-site audits. The audits will examine compliance with specific requirements of the Privacy, Security, or Breach Notification Rules. Auditees will be notified of the subject(s) of their audit via a document request letter. In a desk audit, the required documents must be submitted via a secure portal within 10 days. The auditor will review this information and provide draft findings. Auditees will have 10 days to review and return written comments, if any. The auditor will then complete a final audit report in 30 days. An on-site audit is more comprehensive than the desk audit and will be conducted over 3-5 days; the response timelines are the same. If the desk or on-site audit indicates a serious compliance issue, OCR may initiate a compliance review to further investigate the issue.

How to Prepare

Consider whether your practice has recently conducted a security risk analysis and whether it has appropriate risk management procedures in place. If the analysis identified gaps, work to mitigate those as soon as possible. Ensure that your practice has appropriate device and media controls in place and data is encrypted appropriately and you have appropriate facility access controls. Your staff must have ongoing training on the HIPAA rules, and the training must be documented. Check that you have a Business Associate Agreement in place with all your business associates.

Here are a few more resources:

- HIPAA risk assessment tool for small providers  
  www.healthit.gov
- HIPAA audit program protocol  
  www.hhs.gov/hipaa
- HIPAA Collaborative of Wisconsin  
  www.hipaacow.org

If 2015 was the year of ICD-10, 2016 is the year of HIPAA.

Cathryn Johnson is a senior healthcare consultant with PBC Advisors, LLC, in Oak Brook. The company provides business and management consulting and accounting services to physician practices and hospital systems. For more information, visit www.pbcgroup.com.

Time to Get Fit!

The U.S. Department of Health and Human Services has dubbed May “National Physical Fitness and Sports” month following the lead set by the President’s Council on Fitness. There’s good reason for HHS to focus on fitness for all Americans, not just youth:

- Only one in three children are physically active every day, according to the National Association for Sport and Physical Education.
- Less than 5% of adults participate in 30 minutes of physical activity each day, according to the U.S. Department of Agriculture.
- Only 28-34% of adults ages 65-74 are physically active, according to the Centers for Disease Control and Prevention.

So what can physicians do? The American Academy of Family Physicians offers many suggestions including how to encourage patients to take incremental steps toward increasing physical activity, how to help them set goals, suggesting the use of food and activity journals and providing them with tips for sleeping better at night. To get more information visit www.aafp.org.

May 2016 | www.cmsdocs.org | 5
Techniques to Manage Stress and Prevent Burnout

How physicians and their organizations can combat burnout By Susan Reynolds, MD, PhD

N LAST MONTH’S column, we looked at signs and symptoms of stress and burnout. The 2014 Mayo Clinic study showed that 54.4% of physicians had at least one symptom of burnout on the Maslach Burnout Inventory, and that number is increasing at an alarming rate. The Maslach Burnout Inventory symptoms include: loss of enthusiasm for work/emotional exhaustion; feelings of cynicism/depersonalization; and a sense of low personal accomplishment. While it is important to recognize how widespread these conditions have become, we need to go further and support physicians with specific coping techniques for relieving stress before burnout sets in.

It is also important to remember that stress itself does not cause illness. It is the inability to tolerate stress that does. Some people can tolerate stress much better than others based on genetics, emotional temperament, beliefs, and life experiences.

As previously noted, the imagination is the #1 stressor. Do you regret the past? Do you worry about the future? The imagination is a powerful tool that can also bring us equanimity and relaxation.

To deal with stress and burnout, physicians can develop mindfulness practices, learn better communication techniques, and improve their work-life balance. Ellen Langer has studied the effects of mindfulness practices for over 40 years and found that being mindful, focusing on the present, results in better performance, more positive results and interpersonal interactions, and the ability to find opportunities in challenging times.

Physicians can be their own worst patients. Have you seen patients while under extreme stress? What was your prescription? Work longer hours? Skip vacation time? We all know the benefits of exercise, good nutrition, and adequate sleep, but physicians often neglect these key ingredients for a healthy way of living.

A regular meditation practice can provide a great deal of calm when stressors abound. Relaxation techniques frequently include mental imagery such as the “One-Minute Clock,” the “Golden Energy Ball,” or the “Inner Advisor,” which we present at our stress management workshops.

Organizations can help prevent physician burnout by allowing flexible work hours; monitoring signs and symptoms; and providing physician leadership training, support groups, and CME programs such as those we provide at The Institute for Medical Leadership.

Stanford has developed a unique “time-banking” program that provides “concierge” services for emergency medicine faculty. This program helps bring more balance into these tired doctors’ lives by taking care of mundane tasks. For instance, Stanford’s time-banked services can include meal delivery, housecleaning, babysitting, elder care, movie tickets, grant writing help, handyman services, dry cleaning pickup, speech training, and Web support. As a result, the physicians have more time to spend with family and friends. They also have time to rest and recharge their batteries, thereby living happier lives and preventing burnout.

Susan Reynolds, MD, PhD, is President and CEO, The Institute for Medical Leadership.

There are a variety of good resources available to help physicians understand stress and burnout and learn how to deal with them. Here’s a list of resources that I’ve found especially helpful:

- Mayo Clinic study: Arch Internal Medicine; 2012:172, 1377-1385
- Transitions, William Bridges, PhD
- TheHappyMD.com – Dr. Dike Drummond
- AMA: STEPS Forward
- ACEP: Wellness Book for Emergency Physicians

Resources
PHYSICIAN credentialing is more than just another form to fill out or a minor nuisance. Credentialing is a vitally important, complex, and ongoing process. Without successful credentialing, physician reimbursement for services can be delayed or even denied, causing great harm to your practice’s financial health.

Generally, credentialing is the verification of a physician's experience, expertise, interest and willingness to provide medical care. It encompasses obtaining hospital or facility privileges, as well as successfully enrolling in health plans as a participating physician. Verification is done by going to the “primary source,” which means contacting the entity that provided the education, license, or other credential to verify the accuracy of the information. Most facilities and health plans require annual updates; the re-credentialing process occurs every three years.

But as the volume of required certification elements increases, filling out paperwork takes longer. At the same time, payers need more time to process credentialing paperwork. Unless you are willing to work in a cash-only medical practice and forego all privileges at hospitals, there's not much you can do about the volume of data requested. You can, however, handle your part of the process more efficiently.

Follow these steps to ensure that you and your staff do not get overwhelmed.

Start Early
Plan for credentialing months ahead of time, giving your practice at least 120-150 days to complete the process. Be sure to check state regulations well in advance. Also make a strong effort to gather all the information you need on new physicians in advance, including their start date. Realize that you are working on the payer’s timeline, not your own; each payer has its own internal timeline for application processing. Given the amount of paperwork and time commitment, overlooking or ignoring requests from a payer creates a big financial problem for the physician who cannot bill for services.

Ensure a Solid Workflow
Be sure to maintain all the required forms and documentation because re-credentialing is always just around the corner. Formulate a spreadsheet of payers, hospitals and other third parties that require updates, and record the requirements for submissions and deadlines. You can purchase or lease credentialing software, or outsource the process altogether.

Determine Steps to Take
Communicate with your front desk and billing staff to let them know how to handle a new physician’s scheduling and claims submission during the initial credentialing process. Some payers will retro an effective date once the physician is credentialed. In this case, the physician may be able to see the patient, but the billing staff will need to hold claims until the physician is processed as being in-network. Check with individual payers directly on their policy.

Plan for Medicare Enrollment
Medicare is different than all the other payers. CMS requires physicians to resubmit and recertify the accuracy of their enrollment information every five years, a process known as “revalidation.” CMS has completed its initial round of revalidations and will be resuming regular revalidation cycles.

In an effort to streamline the process and reduce the physician burden, CMS has implemented several improvements. The most efficient way to submit revalidation information is by using the PECOS system on the CMS website or by completing the appropriate Medicare Enrollment Forms. CMS has established a listing of currently enrolled physicians and revalidation dates by which they must revalidate. You can find this information at https://data.cms.gov/revalidation.

Understand Delegated Credentialing
Often a large health system is given authorization by a specific insurance carrier to perform credentialing in-house. A physician who is under such delegated credentialing is not considered credentialed for private practice. Leaving delegated credentialing status can be hard to do. In some instances physicians have left a facility that held their delegated credentialing with a certain payer, but these physicians could not be credentialed in a traditional manner until the health system performing the delegated credentialing contacted the insurance carrier to break the bond. This can cause a physician to suddenly be considered out-of-network with all commercial health plans. Physicians can avoid lapses in network participation if they know how they or a new colleague in their practice is credentialed, and whether it is done by a delegated entity.

Stay Current on CAQH
The non-profit maintains a database called ProView that tracks self-reported professional and demographic information, which can be used by healthcare organizations for physician credentialing. Physicians who regularly update and attest with CAQH find credentialing and re-credentialing much easier.

“Without successful credentialing, physician reimbursement for services can be delayed or even denied, causing great harm to your practice’s financial health.”

Diane Sarka is a credentialing consultant with PBC Advisors, LLC, in Oak Brook. The company provides business and management consulting and accounting services to physician practices and hospital systems. For more information, visit www.pbcgroup.com.
Meningitis can affect everyone, but the current outbreak in Chicago is among gay and bisexual men, particularly those who are living with HIV,” says Sarah Kemble, MD, medical director for the Chicago Department of Public Health’s (CDPH) Communicable Disease Program. Dr. Kemble expressed her concern following the CDPH’s announcement in April that two new cases of meningococcal meningitis have been identified in Chicago men. This means that there are now nine confirmed cases from the Chicago area linked to last summer’s outbreak, all in men who have sex with men (MSM), including one related death last June.

Since May 2015, CDPH has distributed nearly 18,000 vaccinations, of which more than 14,000 have been administered. With these two new cases identified, CDPH is increasing efforts to raise awareness and making affordable vaccines available across the city, while focusing primarily on MSM, the population which is most affected. “Meningitis still poses a serious threat to all men who have sex with men in Chicago and if they have not been vaccinated within the last five years, they could be at risk,” says CDPH Commissioner Julie Morita, MD. “We are continuing our partnership with more than 80 community and clinical advocates to provide free and low-cost vaccinations to protect our most vulnerable residents.”

Though anyone can contract meningococcal meningitis, African-American MSM and men living with HIV continue to be disproportionately affected by this outbreak, says Magda Houlberg, MD, chief clinical officer of Howard Brown Health. “That’s why we recommend to our clients and the gay, bisexual, and transgender community as a whole to get vaccinated to protect themselves and reduce the chance that they can be infected with something as deadly as meningitis. We’d like to provide a ‘herd immunity.’”

Recommendations from CDPH
CDPH has also released a health alert to Chicago’s medical providers about the ongoing outbreak to remind them of CDPH’s vaccination recommendations for the impacted community. CDPH recommends that all men who have sex with men get vaccinated against meningitis. All MSM who are living with HIV will need two vaccinations at least eight weeks apart. Low-cost vaccinations are available at 80 locations around the city. “The vaccine is safe, effective and available free of charge at CDPH clinics. It is also available at most doctors’ offices, clinics and CDPH partner clinics, including many Walgreens, though some partner sites might request a co-pay,” says CDPH’s Dr. Kemble.

She suggests that physicians ask patients who may be at higher risk for meningitis about their sexual history. “Develop a rapport with them, so they feel comfortable. Ask them if they know about the Chicago outbreak, and start a conversation. Ask them about having sex with other men, or even about being intimate with other men, like sharing drinks or cigarettes—it doesn’t have to be sexual contact for the disease to spread.”

Physicians who are caring for patients they suspect of being infected with meningococcal meningitis who have confirmed infections should contact CDPH at 312-746-6034 or 312-746-6088, or call 311 and ask to speak to the CDPH physician on call. For more information about meningitis or the services offered by the Chicago Department of Public Health, you can also visit the CDPH website at: www.cityofchicago.org/health.

Invasive meningococcal disease is a rare but severe bacterial infection that results in serious illnesses including meningitis. Signs and symptoms of meningitis include fever, headache and a stiff neck. This might be accompanied by nausea, vomiting, increased sensitivity to light and general confusion. For those who are unvaccinated and contract the bacteria, symptoms appear three to seven days after exposure. Unfortunately, symptoms are vague and difficult to recognize, and the patient may be in intensive care within 24 hours after symptoms first appear. People can lose limbs, suffer sepsis, as well as neurological defects, and death. Even with antibiotic treatment, at least one in ten people who develop this form of meningitis are expected to die from it.

CDPH will continue addressing multiple aspects of the outbreak including making sure that close contacts of infected individuals receive appropriate preventive measures; educating healthcare providers about diagnosis, treatment and prevention measures; distributing vaccine to healthcare providers; and continuing to educate gay and bisexual men about their need to be vaccinated.

Educating the Community
Believe it or not, it isn’t too early to start gearing up for the next flu season. Marielle Fricchione, MD, who is the medical director for immunizations at the Chicago Department of Public Health (CDPH) gives you the low down on what to expect next season and how to prepare now.

Q: What is CDPH anticipating for the next flu season?
A: First of all it’s important to note that we are still dealing with this year’s flu season. It started late this year and we are still seeing some cases. The strains that we have seen this year, mostly H1N1, were well matched to our flu vaccine so we have seen less influenza-related illness and fewer deaths.

And this just goes to illustrate that every flu season is different. There are numerous factors that contribute to this including the type of flu strains circulating and whether the vaccine offered that year matches those flu strains. Next season, we will again be offering a flu vaccine that protects against four strains of Influenza virus. This quadrivalent vaccine will protect against two Influenza A viruses (including H1N1) and two Influenza B viruses.

Q: How CDPH is preparing for the next season?
A: We plan well in advance to make sure that flu vaccine is available to everyone citywide. This includes holding flu vaccine walk-in clinics from September through December. We will also continue to partner with Walgreens and Aldermen across the city to make flu vaccine available to any resident who does not receive it from their health care provider. Last year we served all of Chicago’s 50 Wards, a total 79 clinics including five Family Flu Days at various locations citywide. We will also continue to assess and improve the tracking of inpatient and outpatient flu data.

CDPH will continue to provide anti-viral treatment and infection control advice to hospitals and outpatient centers that request our assistance. Finally, we are constantly updating our contingency plans to deal with more severe national or international flu outbreaks.

Q: What advice can CDPH give docs regarding their patients?
A: Flu shots are still the most effective way to prevent the flu and we encourage people to get their flu shot every year, not only to protect themselves, but also to protect their loved-ones and those around them who are more vulnerable to the flu. This includes young children, pregnant women, anyone over age 65 and those with chronic diseases like asthma and diabetes. You should also encourage your patients to practice good hand, cough and sneeze hygiene to reduce the chance of transmitting the flu.

As a physician, I see many healthy children every year who need to be hospitalized or even intubated because they got the flu. Unfortunately, most of these children did not receive a flu vaccine. If a patient does contract the flu, there are oral anti-viral medications (Tamiflu) available and recommended to shorten the course and severity of illness.

Q: What resources does CDPH offer for docs?
A: Every week during flu season we publish a Chicago Flu Update at www.chicagohan.org so healthcare providers can keep up to date on trends of influenza illness in Chicago. National weekly statistics can be found on the CDC website at www.cdc.gov. CDPH worked with the Metropolitan Chicago Healthcare Council (MCHC) to publish a very useful healthcare guide for flu that can be found on their site at www.mchc.com. Doctors can go to our website at www.cityofchicago.org for other resources specific to each flu season as well.

CDPH plans to host webinars through EverThrive, an immunization coalition. For further information about preparing for the flu season, physicians and other health care providers should feel free to contact the immunization program at 312-746-5382.

Flu: Nothing to Sneeze At

Ask Dr. Anthony Fauci what one of his biggest concerns is, and he’ll answer, “flu.” As head of the National Institute of Allergy and Infectious Diseases in Washington, Dr. Fauci says he worries about a deadly mutated form influenza that not only spreads very easily, but also has a great degree of mortality. (Think of the 1918 flu pandemic, for example, that killed between 20 million and 50 million people around the world.)

“That’s the reason why we’re putting so much effort into getting what we call a universal influenza vaccine,” Dr. Fauci said at Smithsonian’s Future is Here Festival on April 23. Today, when there’s an outbreak, “you have to scramble to try to get the right vaccine to match the pandemic,” he said. Developing a universal vaccine that would be good against any influenza is “a truly important goal.”

Source: Tech Insider
Toxic Danger for Kids
High risk of ingesting laundry pods

LAUNDRY PODS, those colorful-as-candy packets of laundry detergent, are putting a stain on child safety. “In my 20-plus years as a physician and toxicology expert, I have never seen a common household consumer product that has caused this many injuries to small children,” said Michael Wahl, MD, medical director of the Illinois Poison Center. Dr. Wahl cites a study entitled “Laundry and Dishwasher Detergents in the United States” in the April 2016 issue of The Journal of Pediatrics that found a 17% increase in the number of children under age 6 who were exposed to laundry detergent packets (primarily through ingesting them) from 2013 to 2014. More than 100 children who were exposed to laundry detergent packets required intubation, and two children died.

Nationally, poison control centers received 22,064 calls related to laundry packet exposures among children younger than age 6 from January 2013 through December 2014. During that same time period, the Illinois Poison Center received a total of 1,009 such calls (439 in 2013, and 570 in 2014, an increase of nearly 30% from 2013 to 2014). Last year, the Illinois Poison Center (IPC) and the University of Chicago Medicine Comer Children’s Hospital released a detailed analysis of the threat of laundry pods to young children, finding a nearly ten-fold increase in calls to the IPC about children’s exposure to the product from 2012 to 2014.

Unit dose laundry pods first appeared in U.S. market in 2012. Since that time, hospitals and poison control centers have noted an alarming increase in exposure to these products in children. The statistics on laundry pod-related ingestions are alarming by themselves, but a look at characteristics of the pods provides an explanation for this growing hazard, according to the IPC. “In light of a developing child’s curiosity and use of oral exploration, the attractiveness of the pods, easy accessibility, and the chemical nature of concentrated detergents lead to a high risk of pod ingestion and resultant injury.”

According to the IPC report, “the most common symptoms of laundry pod exposure are nausea, vomiting, coughing, choking, drowsiness, and mouth and throat irritation; symptoms can also include difficulty breathing, respiratory burns and even seizures and comas in extreme cases.”

While laundry pods are not marketed to children, a young child is naturally drawn to the small, brightly colored objects. Marketing studies show that children are attracted to bright colors, as are adults. The difference is that infants and toddlers are developmentally primed to place objects of interest in their mouths. Many laundry pods are produced in bright orange, purple and green to garner attention and encourage purchasing. Even brands with plain white or clear pods have bright exterior packaging. In addition, the size and texture of the pods are appealing. Generally, pods are less than two inches wide. They have a solid feel but with a gelatinous interior similar to many baby teething toys and candy products. A young child often has not developed the skill to distinguish those small pods from toys, pacifiers, teething objects and food products.

Many laundry pod manufacturers provide their products in a large zippered bag, a tub with a lift-off lid or twist top. Currently, there are no mandatory guidelines for safe packaging and for many products, there is minimal to no child resistant packaging. The U.S. Consumer Product Safety Commission released a safety alert in 2013 warning caregivers to lock up laundry pods and keep them out of the reach of children because of easy product access.

Eating detergents in general is problematic because of the nature of soaps. There are multiple chemicals in soap that can endanger the body by causing cell and tissue breakdown.

Laundry pods in particular have a higher risk profile due to the chemical composition of the product. A study comparing laundry pods to detergents noted the higher concentration of surfactants and alcohol in pods contribute to more severe injury. The contents of laundry pods can be particularly caustic to the lining of the mouth and gastrointestinal system because they break down the naturally protective barriers of these tissues. Addition of water can increase the pH of the liquid from 7.5 (similar to water) to 11 (similar to household ammonia).

If doctors suspect that a patient has been exposed to a laundry pod or another potentially harmful substance, IPC recommends that they or the patient immediately call the Illinois Poison Center at 1-800-222-1222. For more information, visit the Illinois Poison Center’s website, http://illinoispoisoncenter.org.
A Step in the Right Direction

Bill aims to curb health plans’ step therapy protocols

PATIENT AND PROVIDER groups, including the Arthritis Foundation, U.S. Pain Foundation, the Epilepsy Foundation of Greater Chicago and others from across the state, are praising State Representative Laura Fine (D-Glenview) and State Senator Julie Morrison (D-Deerfield) for introducing a key piece of legislation aimed at ensuring thousands of Illinois patients have access to the specific medications prescribed by their doctor. House Bill 3549 puts limits on an insurance industry protocol known as “step therapy,” which can require patients to try and fail on a series of medications before being allowed to have a medication their doctor has prescribed. This practice has become pervasive in the insurance industry where it can be required even when the prescribed drug is medically more appropriate for a patient’s condition.

Meanwhile, patients can be greatly delayed from receiving relief for a medical condition that their physician knows how to treat. For example, a patient may be required to start with aspirin before moving up to a prescription pain killer and then finally to the medication their physician prescribed initially.

“Step therapy risks exposing patients to ineffective care and delays the treatment recommended by their treating physician, especially those patients with life threatening and chronic illnesses,” said Michele Guadalupe, Vice President of Advocacy in Illinois for the Arthritis Foundation. “Step therapy should never be used as a barrier to care. We believe the bill being considered in the Illinois legislature will allow for financially responsible care that still keeps patient needs the top priority.”

“Doctors and patients know what’s best for their patients,” said Paul Gileno, President and founder of the U.S. Pain Foundation. “When treating complicated medical issues that many of my members struggle with on a daily basis, a personal understanding of an individual’s condition and symptoms is critical. Patients can’t be treated effectively when doctors are limited as to what medications they can prescribe based on what an insurance provider dictates.”

HB 3549 does not ban step therapy, but rather puts limits on step therapy and fail first protocols. Under the proposed legislation, the step therapy process would become more transparent, requiring health plans to provide a reason(s) for denying a prescription drug. The bill also ensures overrides of the step therapy process if the prescription drug is contraindicated, if the patient has tried and failed on the drug previously, and if the patient is stable on their current prescription medication either from a previous or current health plan.

Similar legislation providing for an override of a health plan’s step therapy protocols has been passed in other states across the country, including Connecticut, Indiana and West Virginia. HB 3549 is now in the state Senate where it awaits further consideration.

For more information, contact the Arthritis Foundation’s Michele Guadalupe at mguadalupe@arthritis.org.
Understanding Your Fair Market Value

Life sciences industry payments to physicians to get increased federal scrutiny

By Jen Johnson, CFA

As compensation transactions between life sciences companies and physicians move into the crosshairs of government agencies, it is imperative that life sciences companies develop a robust internal methodology to ensure that physicians are compensated at fair market value (FMV) for verifiable services.

A classic form of separate and identifiable direct payments to physicians at fair market value (FMV) for otherwise verifiable and legitimate consulting services is often the first step in identifying individual kickback payments. These payments are typically intended to influence physician referrals and could result in litigation, and it is imperative that life sciences companies develop a robust internal approach toward payments to physicians for necessary and legitimate consulting services.

Feds Raise the Stakes

The government’s successes in fighting healthcare fraud has spurred it to increase its investment accordingly. A representative with the HHS Office of Inspector General (OIG) announced in June 2015 that the OIG is in the process of hiring additional lawyers in order to combat healthcare fraud, specifically fraud on the part of physicians providing services to healthcare entities under questionable payment arrangements. Increased scrutiny by the OIG suggests that the agency is no longer willing to wait for whistleblowers to bring qui tam suits, but intends to seek out and prosecute physician fraud on its own.

This initiative by the OIG is surprising given that over 700 whistleblower lawsuits were filed in 2014, representing an increase of approximately 75% over 2009 levels, and clearly illustrates that the agency is not content with the current (albeit increased) rate of healthcare fraud prosecution. Additionally, the OIG has focused in recent years on the utilization of data analytics in its pursuit of Medicare fraud cases, resulting in “almost $15 billion in investigative receivables and more than 2,700 criminal actions in the past three years [since 2012].” These developments indicate that an even greater increase in healthcare fraud and abuse cases will arise in the near future.

Notable Kickback Cases

This prosecution trend is worrisome for life sciences companies in particular, which already face a greater percentage of qui tam lawsuits than other segments within the healthcare sector. For instance, in 2015, pharmaceutical giant Johnson & Johnson reached a $2.2 billion settlement with the DOJ to settle claims that involved the payment of monetary kickbacks to physicians, among other provisions. Omnicare, a leading provider of pharmaceuticals to long-term care facilities and nursing homes, also settled for $116 million in connection with the Johnson & Johnson kickback payments. These settlements highlight the significant risk that life sciences companies run when accused of paying kickbacks to physicians.

Illegal kickbacks do not need to follow the classic form of separate and identifiable direct payments for referrals, but can be implied (and therefore prosecuted) in compensation that exceeds FMV for otherwise verifiable and legitimate physician services. In the 2015 case of Daichi Sankyo, Inc., the pharmaceutical company paid $39 million to settle kickback claims that originated from paying physicians for speaker fees. As all compensation transactions between life sciences companies and physicians move into the crosshairs of government agencies, it is imperative that life sciences companies develop a robust internal methodology to ensure that physicians are compensated at FMV for verifiable services that further a legitimate business purpose of the company.

With the institution of the Physician Payments Sunshine Provision of the Affordable Care Act (also known as “Open Payments”), applicable life sciences companies are required to report all payments to physicians annually on a public website. While certainly aimed at increasing transparency and aiding the decision-making process of informed healthcare consumers, the Sunshine provision reporting requirement also provides a golden opportunity for the OIG and others to collect and analyze physician payment data from many life sciences companies, providing the first step in identifying individual arrangements in which a payment to a physician may exceed FMV.
Developing Physician Service Agreements

Life sciences companies must proactively demonstrate compliance with government regulation in order to avoid investigation and eventual litigation. Before establishing an internal methodology for FMV compensation to physicians, compliance personnel should adhere to the following practical guidelines:

- Determine that a legitimate business need for the arrangement exists (absent potential referrals).
- Fully understand the services being provided as outlined in a written agreement (which should detail payments for identifiable services and be executed before services are performed).
- Determine necessary qualifications for the position such as specialty, credentials, and experience level.
- Identify and screen candidates based on the qualifications above.
- Offer the position to the best candidate.

Though logical, these steps are not always practiced. When physicians are selected through an alternative process, such as marketing department initiatives, it is more likely that the arrangement will fall under regulatory scrutiny. Remember, regulatory authorities will question not only the dollar amount of payments to physicians, but also the legitimate business reason for those payments.

The Fair Market Value Standard

Once it has been determined that the services are required, establishing a FMV hourly rate for these services is the next step to compliance. According to the International Glossary of Business Valuation Terms, FMV is defined as follows:

“The price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms-length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.”

The determination of FMV for physician services is of utmost importance. If the rate payable to a physician is determined to be set at FMV, no excess compensation has been paid to a physician that could be construed as remuneration for referrals; therefore, a company cannot be successfully prosecuted for paying kickbacks to physicians in exchange for referrals.

In the case of physician consulting services to life sciences companies, payments to physicians are most often in the form of an hourly rate, as an hourly approach is suggested by federal regulation for part-time physician services.

Setting hourly physician payment at FMV requires life sciences companies to keep up to date on industry data. For example, a survey conducted by Cutting Edge Information, showed that payments to physicians from life sciences companies from 2006-2011 dropped sharply from an average of $604 per hour to $299 per hour. Although the hourly rates on the whole have remained generally stable since 2011, outdated market studies of FMV compensation rates may provide a false sense of security for companies whose physician payment rates exceed FMV.

The FMV hourly rate should be based on a current and thorough valuation that relies upon objective compensation surveys; as federal regulation recommends, “reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating Fair Market Value.” Many life sciences companies utilize a third party, which can perform the necessary research and create hourly rate tables, to provide a consistent and documented approach to determining FMV. The examination of multiple, objective surveys detailing physician compensation for identical or similar services is essential when constructing an hourly rate table, which should be organized both by specialty and by physician experience tier. Just as the federal government has invested in tools to fight fraud and abuse, life sciences companies ought to also invest in corresponding tools to defend their hourly rate tables, in order to ensure that payments to physicians are consistent with FMV. Finally, once FMV hourly compensation rates are determined, a life sciences company must ensure these payment rates are outlined in physician contracts and implemented.

Best Practices for Compensating Physicians

In spite of the daunting regulatory environment, a well-reasoned compliance program, in which a company can demonstrate its efforts and intentions to operate in accordance with government regulation, is absolutely vital. Larger life sciences companies often have entire departments dedicated to compliance, while smaller companies may neglect the need for compliance entirely. Moreover, while larger life sciences companies typically maintain updated hourly rate tables prepared by a third party, problems tend to occur in the implementation of the physician relationship, as individuals responsible for physician contracting may or may not be fully informed as to the company’s physician compensation policies. Therefore, a well-reasoned compliance program should also include protocols and best practices for engaging and compensating physicians. Taking proactive and logical steps to internally document and standardize legitimate payments to physicians provides a safeguard life sciences companies cannot afford to overlook in light of current regulatory scrutiny.

“A survey conducted by Cutting Edge Information, showed that payments to physicians from life sciences companies from 2006-2011 dropped sharply from an average of $604 per hour to $299 per hour.”
Compounding the Problem

The government cracks down on compounding pharmacy fraud and abuse

By Scott R. Grubman, Esq., and Samuel M. Shapiro, Esq.


ding Data from the Department of Defense (DOD), The Wall Street Journal reported in early February that TRICARE—the federal government payer for military health insurance—paid $1.75 billion in fiscal year 2015 for compounded drugs, including creams. However, after recently conducting parallel federal and state investigations, the various agencies, including the DOD, Department of Justice (DOJ), and U.S. Department of Health and Human Services Office of Inspector General (OIG) suspect that the majority of those bills are fraudulent. Indeed, due in part to the dearth of regulations pertaining to compounding pharmacies, as well as the rates at which federal payers (especially TRICARE) reimburse compounded drugs, the market for such drugs has been rife with suspected fraud and abuse. This article provides an overview of compounding pharmacies and discusses recently uncovered industry schemes.

Compounding: Pharmacies and Drugs

According to the FDA, “compounding” is a practice whereby a pharmacist, physician, or other authorized professional “combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” Physicians may prescribe compounded drugs over ordinary prescription medications for a variety of reasons. For example, a patient incapable of swallowing a pill may seek an alternative compounded medication in liquid form.

Although the FDA retains some authority over compounding pharmacies, most regulatory authority in this area remains with the individual state boards of pharmacy. Moreover, the compounded drugs themselves are not FDA-approved; unlike most other prescription medications, “FDA does not verify the safety, or effectiveness of compounded drugs.”

Originally, 503A of the Food and Drug Administration Modernization Act of 1997 exempted compounded drugs from the FDA’s standard drug approval requirements with the condition that compounded drug providers refrain from advertising or promoting such drugs. However, after the U.S. Supreme Court ruled that the advertising prohibition violated commercial speech rights under the First Amendment, compounding pharmacies have continually engaged in such promotional activities. Marketing blitzes over the Internet and through telemarketers has generated booming sales of compounded drugs since the Court’s 2002 decision, and promotional pitches for products such as compounded scar and pain creams have targeted seniors, military personnel, and even professional athletes.

Indeed, due to TRICARE’s high reimbursement rates for compounded medications, beneficiaries have been subject to “extreme sales tactics,” according to the Military Times. Such tactics have included “cold calls,” Craigslist searches for sales reps and customers, solicitations inside military hospital pharmacies, and even food trucks setup outside of military bases, promising free lunch to TRICARE beneficiaries who sign up for compound medications.

Fraud in the Compounding Industry

Recent settlements and reported investigations of alleged fraud and abuse by compounding pharmacies highlight the government’s increased level of scrutiny over the industry. Although the extent of the allegedly fraudulent practices reaches beyond TRICARE, fraudulent billing for compounded drugs to TRICARE has received the bulk of the government’s attention. Data from the Defense Health Agency (DHA, the arm of the DOD responsible for overseeing TRICARE) shows that TRICARE’s costs for compounded drugs rose from $5 million in 2004 to $514 million in 2014. Both the DHA and the DOJ picked up this surge and, upon investigation, federal authorities uncovered fraudulent schemes that serve as the impetus for the spike in costs.

These investigations, which are currently underway across several states and in several U.S. Attorneys’ Offices, have honed in on potential false claims, kickback arrangements, and even improper auto-refill programs. Although each investigation has its own unique set of facts and circumstances, the typical TRICARE scheme proceeds as follows: Using aggressive marketing tactics, pharmacy sales reps and others hired to promote compound medications market these drugs directly to beneficiaries. Patients may be asked to fill out online forms with their TRICARE number included, or to simply send their insurance information to the sales rep.

The information is then sent along to a physician, who then writes a prescription and sends it to a compounding pharmacy. According to the DOD, “These prescriptions may not be tailored to the beneficiary’s needs, and sometimes the beneficiary never even meets or speaks to a doctor before the pharmacy sends them the drug. Not only that, but often there is little or no evidence that these products are safe or effective...” Indeed, lack of medical necessity and the failure to establish proper physician-patient relationships served as the basis of the DOJ’s allegations of False Claims Act (FCA) violations in two recent settlements with Florida compounding pharmacies.

Moreover, pharmacies across the country have
Avoiding Illegal Arrangements

The Anti-Kickback Statute (AKS) makes it a felony for anyone to offer, pay, solicit, or receive any form of remuneration in exchange for the referral of federal healthcare program business. Thus, the AKS prohibits the payment or receipt of anything of value in exchange for a physician writing a prescription for compounded medications, if claims for those medications are submitted to a federal healthcare program. Any such claims submitted to a federal healthcare program for reimbursement are therefore “tainted” by the kickback and, because violations of the AKS serve as predicates to FCA liability, those claims will also be considered “false” under the FCA, thereby subjecting both parties to treble damages, per-claim penalties, and possible program exclusion in addition to potential criminal liability.

That does not mean, of course, that any remuneration from a compounding pharmacy to a prescribing physician automatically violates the AKS. First, the AKS is an intent-based statute and, as long as no “one purpose” of the remuneration is to induce referrals, there is no violation of the statute. Second, there are a number of “safe harbors” to the AKS and, if a relationship falls under such a safe harbor, there is no violation.

One common safe harbor that could apply to the compounding pharmacy-prescribing physician relationship involves personal services and management contracts. For example, a bona fide speaker program, where the pharmacy pays the physician to speak at conferences and other events about the pharmacy’s products, could fall under the safe harbor if certain requirements are met (the agreement is for at least one year; set out in writing; signed by the parties; covers all the services the physician will provide to the pharmacy; the aggregate compensation is set in advance and is consistent with fair market value and does not take into account the volume or value of referrals). Under this safe harbor, parties are exempted from potential AKS liability. Accordingly, in order to avoid such potential liability, both physicians who prescribe compounded drugs, on the one hand, and compounding pharmacies, on the other hand, must carefully assess their relationships with one another to ensure compliance with the AKS.

Moreover, even when the physician does not receive any financial gain from writing prescriptions, the physician must remain wary of the fact that federal healthcare programs only reimburse for “medically necessary” products and services. Indeed, because healthcare providers must certify up front that all products and services rendered were medically necessary, billing for medically unnecessary services constitutes a false certification and therefore violates the FCA. Thus, physicians who prescribe compounded drugs may further subject themselves to FCA liability if they fail to establish the proper physician-patient relationship necessary to determine whether the patient needs the specially made medications.

A 1999 Fraud Alert issued by the OIG pertaining to improper physician certifications in dealing with medical equipment suppliers and home health agencies parallels the relationship some physicians have with their compounding pharmacies. As the Fraud Alert states:

“Unscrupulous suppliers and providers may steer physicians into signing or authorizing improper certifications of medical necessity. In some instances, the certification forms or statements are completed by [equipment] suppliers or home health agencies and presented to the physician, who then signs the forms without verifying the actual need for the items or services. In many cases, the physician may obtain no personal benefit when signing these unverified orders and is only accommodating the supplier or provider. While a physician’s signature on a false or misleading certification made by mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating Medicare fraud on the part of suppliers or providers. When the physician knows the information is false or acts with reckless disregard to the truth of the statement, such physician risks criminal, civil, and administrative penalties.”

Thus, to avoid such liability, physicians must take care to ensure that each patient for whom a prescription is written is seen personally. Moreover, proper documentation of the visit and the patient’s medication needs will lessen the chance that medical necessity is later questioned.

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Due Process for Doctors
A roadmap for medical professionals facing a potential disciplinary action
By Ryan A. Haas, Esq. and Kimberly T. Boike, Esq.

The Illinois Department of Financial and Professional Regulation (IDFPR) has broad authority to issue a medical license, suspend or revoke a license, or otherwise discipline a license based on evidence of a violation of one or more licensing acts governing the profession at issue. In January 2016 alone, according to the IDFPR’s monthly report, there were approximately 47 disciplinary actions issued by the IDFPR against medical professionals and licensed nurses. The offenses described in the IDFPR’s monthly report, which led to those disciplinary actions, ranged from negligent performance of surgery to writing inappropriate prescriptions to failing to pay state income taxes.

However, the IDFPR cannot act tyrannically or arbitrarily. Illinois courts have long held that a license to practice medicine is a “property right” protected by constitutional guarantees of due process. “Due process of law presupposes a fair and impartial hearing before a fair and impartial tribunal” (Smith v. Dept. of Reg. & Ed.).

When the IDFPR receives information that a healthcare professional may have engaged in conduct warranting discipline, the IDFPR may open an investigation. Depending on the information gathered by the investigator, the IDFPR determines whether to close the file or forward the file to a prosecution unit for further action.

The Informal Disciplinary Conference
When a file is forwarded for prosecution it is assigned to an attorney who can either file a formal complaint or set an informal disciplinary conference. A disciplinary conference is an informal meeting with the IDFPR attorney and one or more licensing board members in the same profession as the individual whose license is subject to potential discipline. Although attendance is not mandatory, the disciplinary conference can be an opportunity to seek a resolution to the issues raised by the IDFPR without the formal complaint process. It is not recommended to attend the conference without an attorney. An attorney can appropriately prepare a respondent and assert the respondent’s rights.

While no transcript of the conference will be taken, the IDFPR attorney and board members who attend will certainly be influenced by what is stated during the conference. The disciplinary conference often ends with the IDFPR presenting a formal settlement offer, which could take the form of an administrative letter of warning, which is not reportable to the National Practitioner Data Bank (NPDB), or could include formal discipline, which is reportable. The settlement offer is merely an offer to resolve the case without further action and can be accepted, rejected or the respondent can make a counteroffer. If the settlement offer is accepted, a consent order will be prepared and then submitted to the full board and IDFPR director for approval.

The Formal Complaint
In many cases, a formal complaint is filed without the opportunity to participate in a disciplinary conference. If so, it is strongly recommended that the respondent retain an attorney soon after being notified of the complaint. A formal complaint will detail the charges and action sought by the IDFPR—probation, suspension or revocation of the license. The respondent must file an answer to the complaint. After the answer is filed, a preliminary hearing is set before an Administrative Law Judge (ALJ) to discuss schedules for discovery and hearings.

After the completion of discovery, the ALJ will conduct an evidentiary hearing, following procedural rules. The IDFPR must prove the alleged violation with clear and convincing evidence, which generally requires expert testimony in cases involving allegations of gross negligence. Respondents may present expert testimony and other evidence to rebut the IDFPR’s assertions.

At the conclusion of the hearing, the ALJ will enter a recommended decision. The ALJ’s recommendation will then be reviewed by the Medical Disciplinary Board, which may either affirm or reject the ALJ’s decision. The director has the ultimate authority to adopt the Board’s recommended decision.

Appeal to Circuit Court
The director’s decision is considered the IDFPR’s final order. If the decision is not favorable to the respondent, an appeal under the Administrative Review Law may be initiated in the appropriate circuit court. The circuit court judge may affirm or reverse the director’s decision, which then may be appealed to the appellate court.

Medical professionals facing a disciplinary action before the IDFPR must be proactive in asserting their due process rights. Consulting with legal counsel early in the process is critical to ensuring those rights are protected.

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A recent trend has been the increasing number of civil settlements and criminal convictions against physician practices that purchased foreign prescription drugs and medical devices that have not been approved by the U.S. Food and Drug Administration (FDA) for use in the United States. One common scenario is when a physician practice or clinic purchases these non-FDA approved drugs or medical devices unwittingly. In this case, a clinic may purchase drugs or medical devices from a local supplier who has obtained these non-FDA approved drugs from another company.

Recent civil False Claims Act (FCA) settlements by orthopedic clinics in Tennessee and Virginia by the U.S. Department of Justice (DOJ), guilty pleas by oncologists in Missouri and California, and enforcement by the FDA Office of Criminal Investigations highlight the significant liability physicians may incur from purchasing non-FDA approved drugs from Canada and other countries, or from unauthorized suppliers. The clear message from these enforcement actions, as well as recent changes to federal and state law, is that:

Physicians are ultimately responsible for knowing the source of the drugs and medical devices they purchase for their patients. Physicians must also ensure that they are purchasing drugs and medical devices from an approved supplier in their state.

A bit of background: How it works

Physician offices and clinics are often contacted by pharmaceutical and medical device distributors through mass advertising campaigns, including blast faxes, phone calls, direct mail, and online marketing. These distributors often pursue clinics and hospitals with offers to sell physician-administered drugs, including injectable drugs.

But not all of these distributors are reputable. Disreputable distributors will often break down large shipments of drugs into multiple small shipments in order to smuggle foreign pharmaceuticals across the U.S. border. These smaller shipments may then be sent to addresses in multiple states and locations to companies that are listed using false names. Custom forms may falsely state the contents and value of the shipments. Local companies in the U.S., referred to as drop shippers, receive the packages, remove indicia that they were from abroad, and then re-ship them to doctors and clinics in the U.S. so that the packages have a U.S.-based return address. According to the FDA, these drop shippers store the drugs and medical devices in the basements of their private residences, often in violation of safety regulations requiring that pharmaceuticals be stored at cool temperatures.

In some cases, foreign non-FDA approved drugs and medical devices are delivered directly to physician clinics from pharmaceutical companies or suppliers in another country. A local drop shipper will generally have UPS pick up this package from a clinic and re-package the drugs or medical devices in a box that does not contain any postmark or return address of another country, and have it re-delivered to the clinic.

Recently several companies and individuals have pleaded guilty to smuggling and selling misbranded prescription drugs and unlicensed (non-FDA approved) drugs to local suppliers and physician clinics in the U.S.0. Apparently, the FDA Office of Criminal Investigations is investigating local suppliers or drop shippers and physicians who may have purchased prescription drugs and devices from these companies.

Beginning Jan. 1, 2015, the Drug Supply Chain and Security Act requires all healthcare providers who dispense or administer prescription drugs to patients must purchase these products only from authorized trading partners (also commonly referred to as approved suppliers) who are licensed by or registered with the state or federal government. Authorized trading partners include wholesale distributors, manufacturers, re-packagers, and dispensers. In short, healthcare providers, including physicians, are responsible for assuring that their immediate or local suppliers are “authorized,” which means licensed by the appropriate federal or state agency.

The False Claims Act settlements discussed below include several aspects of the packaging that would alert physician practices that the drugs or medical devices may be from a foreign country, and not FDA-approved.

False Claims Act Settlements

On Jan. 24, 2014, the DOJ announced that two orthopedic practices would pay a combined $1.85 million to resolve state and federal False Claims Act allegations that they knowingly billed state and federal healthcare programs for osteoarthritis medications known as viscosupplements that were
distributing in foreign markets and then reimported to the U.S. The two settlements involved orthopedic clinics in Tennessee and Virginia.

Viscosupplements are substances injected into a joint to treat arthritic knee pain. The products are distributed under brand names such as Synvisc, Hyalgan, Orthovisc, and Supartz and are approved by the FDA as injectable Class III medical devices to treat osteoarthritic knee pain. Viscosupplements are reimbursed by Medicare, Medicaid, and other federal health care programs.

The government alleged that the clinics knowingly purchased deeply discounted viscosupplements that were reimported from foreign countries, and then billed the state and federal health care programs even though such reimported viscosupplements are not reimbursable by those programs. The DOJ contended that the reimported products contained labeling in foreign languages and in English for additional uses not approved in the U.S. This demonstrated that the products were reimported, and thus there was no reassurance they were safe or had not been tampered with or were stored appropriately.

The complaint against the Tennessee and Virginia clinics was filed in 2012 under the whistleblower provisions of the civil False Claims Act by a representative for a pharmaceutical manufacturer of one of the viscosupplements. An interesting aspect was that the whistleblower was retained by the pharmaceutical manufacturer to educate medical providers about the use of Synvisc. According to the DOJ, the reimported viscosupplements contained labeling and packaging that were not approved by the FDA, including labeling in foreign languages as well as labeling for uses that were not approved in the U.S.

**Buying and Selling Misbranded Prescription Drugs**

Several companies and individuals have recently pleaded guilty to smuggling and selling misbranded prescription drugs, as well as to wholesaling unlicensed prescription drugs in the U.S. Physicians who purchased these drugs have also pleaded guilty to buying and selling, as well as dispensing, foreign, misbranded drugs to their patients.

Government allegations that prescription drugs and devices were misbranded have been based in part on the following: (a) they were not in possession of a person who regularly engages in the storage or wholesale distribution of prescription drugs or devices; (b) there was not a label that contained required language limiting their use to prescription only; (c) prescription drugs failed to have the FDA-approved labeling and/or the “Rx only” symbol; and (d) the drugs and devices were misbranded in some cases because they did not have certain language required by the Food Drug and Cosmetic Act (FDCA) in English.

According to the FDA, a drug may be considered misbranded even if it is identical in composition to an FDA-approved drug made by the same manufacturer in the same facility. It is important to keep in mind that misbranding is a strict liability offense under the FDCA. Anyone who participates in a violation can be convicted of a crime even if there is no intent to violate the law.

On March 30, 2015, a Joplin, Missouri, oncologist pleaded guilty in federal court to dispensing foreign, misbranded drugs to his cancer patients. The oncologist had ordered prescription cancer drugs from a company based in Winnipeg, Canada. This Canadian-based company had sold drugs to the oncologist that had been obtained from foreign sources and which had not been approved by the FDA for use in the U.S.

According to the DOJ, the labeling for the prescription drugs the oncologist purchased was different from the versions the FDA had approved for distribution in the U.S. For example, the DOJ stated that the drugs did not have labels bearing the symbol “Rx Only,” and the labeling for some of the drugs was in one or more foreign languages. Some of the prescription drugs lacked mixing and use instructions in English.

The oncologist submitted reimbursement claims for these drugs and their administration to Medicare and Medicaid, Tricare, and private health insurance programs. The oncologist paid $971,854 in restitution to Medicare, Tricare, Missouri Medicaid, and Oklahoma Medicaid and Kansas Medicaid programs.

On Jan. 29, 2014, the U.S. Attorney’s Office in the Northern District of Ohio announced that seven Ohio oncologists were ordered to pay $2.6 million after pleading guilty to misdemeanor charges of causing the shipment of misbranded drugs in violation of the FDCA. These drugs from Canada were not approved by the FDA for introduction to the U.S. Each physician was required to pay fines and restitution, ranging from $158,418 to $1,139,532, and was sentenced to probation. The seven oncologists were charged with purchasing cancer drugs from Canada, including Zometa, Kytril, Taxotere, Gemzar, and Eloxatin, and providing the drugs to their patients.

In December 2013, the DOJ announced the guilty plea of a Texas oncologist for introducing misbranded cancer drugs into the U.S. from Canada. According to the government, the drugs were not approved for distribution or use in the U.S. and did not satisfy labeling requirements. The oncologist used the drugs interchangeably with FDA-approved versions on his patients and filed claims with federal and state health care programs, including Texas Medicaid, Medicare, and Blue Cross and Blue Shield. The physician agreed to repay over $1,000,000 for the reimbursements that he received, and is awaiting sentencing that could result in up to one year in prison and up to $100,000 in fines and penalties.
Purchasing Unapproved Prescription Drugs

On June 28, 2013, the U.S. Attorney for the Southern District of California announced that a La Jolla oncology practice was sentenced to pay a $500,000 fine, forfeit $1.2 million and make restitution to Medicare in the amount of $1.7 million for purchasing unapproved foreign cancer drugs and billing the federal program. The practice admitted that it purchased $3.4 million of a foreign cancer drug, knowing that the drug had not been approved by the FDA.

The practice admitted that it was aware the drugs were not approved by the FDA for use in the U.S. because: (a) the packaging and shipping documents indicated that drugs were shipped to the office from outside the U.S.; (b) many of the invoices identified the origin of the drugs and intended markets for the drugs as countries other than the U.S.; (c) the labels did not bear the “Rx Only” language required by the FDA; (d) the labels did not bear the National Drug Code (NDC) numbers found on the versions of the drugs intended for the U.S. market; (e) many of the labels had information in foreign languages; (f) the drugs were purchased at a substantial discount; (g) the packing slips indicated that the drugs came from the United Kingdom; and (h) the office had received a notice from the FDA in October 2008 that a shipment had been detained because the drugs were unapproved.

In a related False Claims Act lawsuit filed by the U.S., the physician-owner of this oncology practice paid in excess of $2.2 million to settle allegations of submitting false claims to the Medicare program. (Medicare does not cover prescription non-FDA approved drugs.)

FDA Warning Letters to Physicians

Prior to the FCA settlements and guilty pleas by physicians, the FDA had sent the physicians warnings about the risks of purchasing medications from foreign manufacturers or local unlicensed suppliers (drop shippers). Generally, subsequent to a guilty plea or conviction of a pharmaceutical company or its distributor in the U.S. for selling misbranded and unapproved drugs, the FDA has sent warning letters to physicians who may have purchased unapproved drugs from these companies or their suppliers.

For example, the FDA sent a warning letter to certain physicians the agency believed had purchased unapproved foreign drugs or unapproved injectable devices distributed by Gallant Pharma International, Inc. Among the 12 individuals convicted by purchasing from Gallant were a doctor and an office manager, for their roles in distributing drugs and devices that had not been approved by the FDA for use in the U.S. The FDA letter to physicians listed 39 drugs, primarily unapproved chemotherapy and injectable cosmetic drugs, which Gallant had sold in the U.S.

In March 2016, the FDA sent letters to physicians who the agency believes may have purchased counterfeit Botox and vicosupplements, such as Orthovisc and Synvisc from an unlicensed supplier, TC Medical. This unlicensed supplier pleaded guilty last May to smuggling and selling misbranded prescription drugs in the U.S. In that warning letter to physicians, the FDA stated, “receiving misbranded drugs and devices in interstate commerce and delivery or offering to deliver these drugs and devices for use on others violates federal law.”

FDA Guidance for Physicians

In their letters, the FDA also included recommendations to help physicians safely purchase drugs and devices from pharmaceutical distributors.

These recommendations included:

- Buy directly from the manufacturer or a wholesale drug distributor licensed in your state.
- Beware of offers too good to be true, including aggressive marketing tactics and deep discounts, on prescription drugs.
- Buy only from state-licensed wholesale drug distributors.
- Check for the following signs that a prescription drug may be unsafe, ineffective or fake:
  - label is not in English
  - packaging looks slightly different from the FDA-approved product
  - product name differs from the name of the FDA-approved drug
  - dosing recommendations are unfamiliar
  - safety information or warnings are missing
  - dosage forms or administration is different
- Pay close attention to patient feedback.

In addition to potential prison time and fines for misbranding or other violations of federal and state law, the potential consequences for physicians of purchasing medical devices or drugs through unauthorized distribution channels can include criminal and civil false claims liability, repayment obligations, exclusion from federal health care programs, liability to patients, and loss of professional licenses or hospital privileges.

Physicians should stay in front of these issues and adopt compliance practices to ensure they are purchasing drugs and medical devices from authorized suppliers. In the event they later discover that they may have purchased unapproved drugs or medical devices, physicians should consider self-disclosure or other reporting route to the applicable governmental agency.

The information in this article is intended for informational purposes only, and should not be construed as legal advice on the topics addressed. Clay J. Countryman, Esq., is a partner with Breazeale, Sachse & Wilson, LLP, in Baton Rouge, La. He can be reached at: Clay.Countryman@bswilp.com.
Safety in Numbers
Insurance mergers and MACRA could spur physician practice consolidation By Bruce Japsen

The threat of health insurers getting even larger, the shift to value-based care and a government performance measure initiative are triggering an unprecedented wave of consolidation among doctor practices. The days of the standalone practice are nearing extinction in some parts of the country while even practices with 10 physicians now makeup less than half of the nation’s medical groups, according to new data from physician staffing organizations and medical associations.

The consolidation afoot doesn’t always mean more physicians will be selling their practices to larger players like hospitals or health systems or that physicians are destined to become an employee of a medical group or hospital. But physicians are increasingly finding safety in numbers given the information technology needs, reimbursement pressures from a dwindling number of insurers and the move away from fee-for-service medicine. “There will be horizontal and vertical integrations and it’s happening in all sides of healthcare,” Zack Cooper, a Yale University professor of public health and economics said on a recent panel at the Association of Health Care Journalists annual meeting. “It’s tremendously important.”

Losing Leverage
A key driver figuring in doctor consolidation is that they are going to lose leverage as a standalone or smaller practice with the nation’s largest health insurers getting bigger. Aetna, for example, is expected to close on a deal in the second half of this year to buy Humana while Anthem, which has customers in nearby Wisconsin and Indiana, is poised to grow in Chicago once its purchase of Cigna is finished, also before the end of this year. Nationally, it would bring the five largest publicly traded health plans from five to three and in Chicago, it would eliminate two large health plans in Cigna and Humana, which is a large provider of Medicare benefits to seniors. Meanwhile, Centene, which has a large Medicaid business in Cook County, purchased HealthNet, which has much of its business elsewhere.

“At any level, people seem to gravitate to larger entities and we are seeing it far past that whether you are just a regional or urban medical group or in small town America,” Travis Singleton, senior vice president of Merritt Hawkins, a subsidiary of AMN Healthcare said in an interview with Chicago Medicine.

Consolidation in the healthcare industry is happening at an unprecedented pace with “merger and acquisition activity” jumping by 14 percent in 2015 to a new record of 1,498 transactions, according to the research firm Irving Levin Associates. “Three years into the Affordable Care Act, more consumers have health insurance and the shift to bundled payments is under way,” said Lisa Phillips, editor of Health Care M&A News of the third year since broader coverage became available under the health law. “Health care providers, health insurers and pharmaceutical companies are all looking for greater scale and cost efficiencies.”

Among medical groups, deal volume jumped nearly 50 percent to 88 last year from 60 in 2014, Irving Levin reported. And the Levin report doesn’t generally track individual doctor practices or small groups. “If you are a two and three FTE (full-time equivalent) group you have to be affiliated at whatever level to survive,” Singleton said. “If you don’t have a seat at the table, you are on the menu.”

Analysts say doctors in the Chicago area are sure to lose leverage because the market already faces a dominant insurer in Blue Cross and Blue Shield of Illinois. Blue Cross rivals getting bigger means less leverage for providers. “There are many forces at play for small independent practices to make it work,” Kevin Sears, executive director of market and network services at the Cleveland Clinic said during a panel discussion on national implications of mergers and consolidation at the Association of Health Care Journalists meeting in April in Cleveland.

The MACRA Effect
In addition to health insurance consolidation, experts like Sears and Yale’s Cooper see doctors being forced to consolidate into a larger system because they won’t be able to afford the time and additional bureaucracy associated with the coming measures that will be instituted in the next three years as required under the Medicare Access and CHIP Reauthorization Act of 2015 known as “MACRA.” Though MACRA repeals the flawed sustainable growth rate (SGR) formula that cut payments to physicians, its merit-based incentive payment approach is going to require a new set of headaches for physicians. MACRA’s merit-based incentive payment system brings together three existing reporting programs: the physician quality reporting system, the value-based payment modifier and meaningful use.

“One of the unintended consequences of MACRA could drive them out of business and into the arms of larger (systems),” said Sears who works with physicians and their affiliated practices across the country. “You need infrastructure
to do the reporting and analytics to manage the care. I’m not sure it’s the best thing for the industry, but it’s the reality.”

To be sure, the most recent data available from the Physicians Foundation shows 17 percent of doctors were in solo practices, which is down from 25 percent in 2012. Merritt Hawkins, which does the survey of 20,000 doctors for Physicians Foundation, expects the number of solo practices to dwindle even more when its new report comes out later this summer. Cleveland Clinic’s Sears said his research shows that “independent” providers have dwindled to 10 to 15 percent in many metropolitan markets across the country. Chicago could be next, these analysts say.

On the flip side, 28 percent of physicians nationally were considered part of larger practices of 51 or more doctors in 2014, which was up sharply from 20 percent in 2012, the Physicians Foundation data shows. “Advocate Medical Group has expanded by more than 30 percent over the last two years—making it the largest employed physician group in the region,” said Dr. James Dan, president of Advocate Medical Group. “Comprised of more than 1,700 physicians and advanced practice clinicians, new members cite their need for business and administrative support as a top motivator along with their desire to become part of a top-performing, integrated, multi-specialty network.”

Though definitions vary on what a small practice is, an American Medical Association analysis released last year shows the majority of U.S. physicians “still work in small practices.” It’s data showed 60.7 percent of physicians were in small practices of 10 or fewer physicians and the number changed little between 2012 and 2014.

**Avoiding Antitrust Scrutiny**

Given the smaller sizes of practices, it could help blunt antitrust scrutiny that health insurers and large hospital systems are facing. Justice

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| **Grand Total**           | 1,498      | 1,318      | 14%           |

Source: Health Care M&A News, January 2016
Department and Federal Trade Commission (FTC) attorneys have looked into doctor practice consolidation, but it has been in cases were large multi-society groups with dozens of doctors have merged with a similar or larger sized group. An often-cited case against Boise, Idaho-based St. Luke’s Health System resulted in the hospital operator losing in court and was forced to unwind its acquisition of Saltzer Medical Group, considered to be that state’s largest multispecialty medical group.

In Illinois, the FTC has its sights set on derailing the largest ever merger of medical care providers here, saying the combination gives the two systems more than 50 percent market share in the north shore suburbs. The FTC has said the merger of Advocate Health Care with NorthShore University HealthSystem would “significantly increase the combined system’s bargaining power with health plans, which in turn will harm consumers by bringing about higher prices and lower quality,” said Debbie Feinstein, Director of the FTC’s Bureau of Competition.

But most doctors shouldn’t have to worry that the FTC or Justice Department will come after them should they decide to join the consolidation wave, particularly in a large market like Chicago that is quite fragmented, particularly when it comes to physicians. Because consolidation tends to be among a doctor going to work for someone else as an employee or being bought out by a smaller practice, there’s less reason to worry about antitrust scrutiny. “Small deals will muster relatively easier because there are clear efficiencies,”

David Balto, a Washington attorney and former policy director at the Federal Trade Commission, said in an interview with Chicago Medicine. “Larger transactions which may create firms with market power will get much more attention.”

To defend against any antitrust allegations, attorneys say insurers may have to prove that their efforts are keeping costs under control for consumers and are making healthcare more efficient. Balto said regulators weigh “market power on one side and efficiencies that come about from economies of scale.” Diverse systems and services together that may improve quality and lower costs are less likely to have a problem. “My problem with health insurance mergers is that their efficiency story is pathetic,” Balto said.

Bruce Japsen is a health care journalist, speaker, author and regular contributor to Chicago Medicine who also writes for Forbes. He is the author of the book, “Inside Obamacare: The Fix For America’s Ailing Health Care System” and is a regular analyst on health, business and political topics to WBBM Newsradio and WTTW television’s Chicago Tonight program and Fox News Channel’s Forbes on Fox. He can be reached at brucejapsen@gmail.com.

MACRA Basics

BACK IN APRIL 2015, the Medicare Access and CHIP Reauthorization Act (MACRA) was signed into law. Not only does MACRA permanently repeal the flawed Sustainable Growth Rate (SGR) formula for determining Medicare payments for clinicians’ services, but it also establishes a new framework that rewards physicians for value over volume and streamlines other existing quality reporting programs into one new system. Beginning in 2019, the Centers for Medicare and Medicaid Services (CMS) will implement a new two-track reimbursement system under which providers will be rewarded for delivering high-quality, cost-effective care and encouraged to shift toward alternative payment methodologies. The two tracks are a Merit-based Incentive Payment System (MIPS) and an Alternative Payment Model (APM).

MIPS can be considered an enhanced fee-for-service model. It replaces three Medicare quality and payment programs: the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VBPM), and the Medicare EHR Incentive Program (Meaningful Use). MIPS combines these programs into a single consolidated program with four with four weighted performance categories: quality (30%), resource use (30%) and Meaningful Use of certified EHR technology (25%). Based on their performance in the categories, providers receive a composite performance score that ranges from 0 to 100. Like current Medicare quality programs, MIPS will incorporate penalties and bonuses that grow to 9% in 2022 and beyond.

As an alternative to MIPS, which is largely rooted in fee-for-service reimbursements and will have relatively flat reimbursement increases over the next 10 years, APMs offer significantly higher financial returns for taking even greater risk. Physicians participating in APMs will not be subject to MIPS adjustments and will instead receive lump sum incentive payments. To qualify for an APM, entities must: use quality measures comparable to measures under MIPS; use certified EHR technology; bear more than nominal financial risk or is a medical home expanded under the CMS Innovation model; and has an increasing percentage of payments linked to value through Medicare or all-payer APMs.

To encourage physicians to participate in APMs and to help offset investments or other costs incurred, the legislation provides 5% bonus payments from 2019 to 2024 for physicians and physician organizations. Qualification for this incentive is based on receiving a portion of Medicare revenue through an APM. To earn the 5% incentive payment in 2019 and 2020, at least 25% of Medicare revenues must be through an APM. This percentage increases in 2021 and 2022 to 50% of Medicare revenues through an APM in order to receive the 5% incentive bonus.
Communication saves lives.
Just ask Dr. Singh.

When Pamela felt a flutter in her chest and feared she might faint, she went straight to the ER. Emergency physician Dr. Singh discovered a suspicious finding on Pamela’s EKG, and sent an image of the recording to the on-call cardiologist via DocbookMD. The cardiologist quickly confirmed SVT, a condition requiring immediate medical intervention. The potentially life-threatening episode was resolved within minutes—rather than hours—and Pamela was safely discharged home. All thanks to some quick thinking and the secure mobile app, DocbookMD.

DocbookMD is a free benefit of your CMS membership.
Learn more about the app at docbookmd.com.
MEMBER BENEFITS

If you are like most physicians, you probably have strong opinions about the state of health care today. Fortunately, you don’t have to just sit back and let things take their own course. Through your Chicago Medical Society and the Illinois State Medical Society, you have ample opportunity to make your opinions heard—and even better, acted upon. Here’s how.

Join a Committee
All Chicago Medical Society (CMS) members are invited to serve on a committee—we have one for every interest. As the backbone of our organization, committees anticipate and respond to trends and issues in health care. Regardless of your practice type, age, or specialty, policymaking is open to everyone. The following pages showcase opportunities for students, residents, and physicians to make their voices count, and watch their dues dollars at work.

Your involvement can be active participation or simply learning and listening. Committees study issues brought by other members, leadership, or outside organizations. As a committee member, you’ll hear testimony, shape resolutions, and have ample opportunity to share your opinions. The electronic meeting format expedites committee discussion.

Grassroots committees make your Medical Society stronger, furthering policies and action on your behalf. Appointments to CMS committees begin each spring. For details, or to sign up for a committee, please call 312-670-2550, or email Ruby Bahena at rbahena@cmsdocs.org.

An Open Invitation
Here’s your chance to have a voice in medicine

The CMS Public Health Committee had a bumper crop of resolutions to consider in 2015. Not only did these measures address patient health, but also the educational needs and well-being of physicians. All CMS committees are open to members, residents and students.

Academic Physicians Committee
Purpose: Formed to improve CMS’ representation of physicians involved in academic medicine, this committee addresses the unique regulatory and financial issues that affect academic physicians, and provides a forum to discuss them. The committee is responsible for researching the feasibility of policies, activities and services to best serve the needs and interests of academic physicians.

Notable work: In 2016, advocating for greater investment in medical research, extension of the tax credit, etc.

Health Care Economics Committee
Purpose: Monitors local managed care trends, health delivery service and quality; advises CMS of significant trends, reviews the actions of the professional liability insurance industry, informs CMS about health planning in Chicago and Suburban Cook County; evaluates the effects of physician reimbursement and medical policies proposed by the federal government and third-party payers.

Notable work: In 2016, launching narrow network bill in the General Assembly.

Physicians Advocacy Committee
Purpose: Represents and protects the rights, responsibilities, and interests of physicians in all modes of medical practice, including solo, group, employed, and academic; and in all hospital medical
staff issues, including physician self-governance, credentialing, medical policy development, peer review, patient advocacy, and quality of care; resolves complaints, disputes, or conflicts involving any physician member of a medical staff and any structured medical entity.

Notable work: In 2016, investigating hospital charges for uninsured patients, biological drug substitutions by pharmacies, automated FAX refill requests.

**Public Health Committee**
Purpose: Reviews and responds to requests for advice, opinion, or program approval directed to CMS by any health department, municipal health committee, or public health body in Cook County. In addition to drafting resolutions, the committee studies local health issues and initiates contact with groups on matters of concern to medicine.


**Resolutions Reference Committee**
Purpose: Reviews new policy and action resolutions from members and the leadership; holds hearings on those resolutions, and makes recommendations to the Council.

Notable work: In 2016, considered 20 resolutions, sending most on to ISMS and the AMA.

**Council on Medical Staff Leadership**
Purpose: Addresses the needs and interests of medical staff leadership, as well as the unique issues affecting medical staffs and hospitals. The council is composed of medical staff presidents, presidents-elect, secretaries, and representatives of the American Medical Association’s Organized Medical Staff Section. The services offered include: quarterly meetings to discuss issues affecting hospitals; the development of educational programs; the preparation of newsletters to inform staff of important medical, legal, and legislative updates; and research on topics of interest or concern.

**Employed Physicians Committee**
Purpose: Addresses the concerns of employed physicians through education and advocacy. Efforts in this area include educational programs on employment contracting, employee rights, and benefit resources.

**Women Physicians Forum**
Purpose: Addresses the unique needs and interests of women physicians in Cook County. As the local counterpart of the ISMS Women Physicians Forum, the group is structured to focus on three key areas: (1) representing and advocating on behalf of women physicians; (2) networking; and (3) offering services specific to women physicians. The Women Physicians Forums of CMS and ISMS provide the means for a strong representative voice on behalf of the growing number of women in medicine.

**Young Physicians Group**
Purpose: Assists new physicians in their transition from training to a professional career. A young physician is defined as a doctor younger than 40 years of age or a physician within the first eight years of professional practice following residency and fellowship training. This resource helps facilitate the transition process and provides networking, educational and mentoring opportunities.

**Communications /Technology Committee**
Purpose: Monitors the world of technology, and informs and educates members on the use of computer and technology applications in the clinical setting and for personal use.

**Bylaws /Policy Review Committee**
Purpose: Reviews suggested changes to the CMS Bylaws, and recommends amendments to the Council when appropriate; reviews Council actions and statements in the CMS Policy Manual for appropriateness and timeliness.

**Continuing Medical Education Committee**
Purpose: Ensures that CMS is in compliance with the Essential Areas and Standards for Commercial Support (SCS) of the Accreditation Council for Continuing Medical Education (ACCME); initiates, implements and evaluates CME programs; and assists related groups in structuring CME programs under joint sponsorships.

**Long-Range Planning Committee**
Purpose: Ensures that CMS has a well-conceived five-year strategic plan that includes an analysis of the Society’s trends, strengths and weaknesses and the environment of medicine; prescribes actions to position CMS for the future. The plan is updated annually.

**Membership /IMG Committee**
Purpose: Provides a vehicle for CMS senior physicians to support CMS through outreach, education, and mentoring.

**Subcommittee on Joint Sponsorship**
Purpose: Helps plan CME activities and provides detailed review of all applications received from related organizations for joint sponsorship; advises the full CME Committee on trends, concerns, and requirements; assures that CMS activities and joint sponsorship programs are in full compliance with the Essential Areas and Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME).

**Credentials /Elections Committee**
Purpose: Determines the number of voting members present during Council meetings, announces quorums, acts as tellers, if necessary, and takes charge of all general elections.

**Get Involved with Advocacy**
CMS’ eight geographic districts are drawn to correspond with actual legislative districts, giving each proportional...
representation on the Governing Council. This democratic body meets quarterly. Its number one purpose: setting an advocacy agenda. In addition to the eight districts, CMS formed a medical student section, which represents the seven medical schools in the Chicago area, and a resident section. To better represent Chicago’s diverse physician body, the Governing body allot seats to hospital medical staff, specialty societies, and ethnic medical associations. Whatever your background or practice mode, there’s a place for you on our Council.

And now we are calling for new voices for 2016-2017! As healthcare delivery changes, so must CMS advocacy. To that end, we are seeking fresh voices to represent the Chicago-area’s 61 hospitals and health systems. Please consider serving your district colleagues in this way. Appointments are made in the spring and summer for one-year and two-year terms.

The Resolutions Process

Ever wonder how a resolution is born? If committees form the Society’s backbone, resolutions provide the lifeblood. CMS is the starting point for county, state, and national efforts, vetting ideas in their embryonic state. Without CMS, Illinois would be bereft of important public health laws and physician protections. Illinois would cease to be a leader at national AMA meetings. Although CMS is a county medical society, we lay the groundwork for legislation in Springfield and Washington, DC, on your behalf.

Resolutions are not hard to write. They are simple proposals that outline a problem and a desired solution. Resolutions can provide specific guidance to lawmakers, or direct your medical societies to act on a particular issue. A resolution allows rank-and-file members to ultimately shape the advocacy agenda of CMS, ISMS, and the AMA.

Once you submit your resolution to CMS, a committee will give it prompt attention. You will be asked to give testimony. The committee then recommends the best course of action to the CMS Governing Council, which may approve or amend or study a resolution.

If your resolution is approved, the next step is for your Society to submit it to the ISMS Annual House of Delegates meeting where, once again it will be approved, amended or recommended for study. If it passes through ISMS and is of concern on a national level, your resolution will then be forwarded to the AMA’s Annual House of Delegates meeting. And from there, your fledgling resolution could become national policy!

Here’s just a very small sampling of influential resolutions that shaped national policy:

- Educating Medical Providers as First-Line Responders to Stop Human Trafficking
- Stimulate Antibiotic Research and Development
- Headphone Distraction Awareness Campaign
- Medicare Records Retention and Overpayment Recoupment
- Medicare Balance Billing
- Limiting Sale and Distribution of Energy Drinks to Minors
- Banning Artificial Trans Fats
- Preventing Allergic Reactions in Food Service Establishments
- Safer Chemicals Policy
- Modernization of the Toxic Substances Control Act of 1976
- Physician Participation in State Executions
- SIDS Research
- Toy Safety
- Internet and Child Pornography
- Nutrition Standards for Food Banks and Repositories
- Deductibility of Student Loans
- Mandatory Minimum Hospital Stays for Post-partum Women
- New CPT Code and Reimbursement for Physicians Conducting End-of-Life Discussions
- Banning the Use of e-Cigarettes Indoors
- Banning Smoking on Airplanes

If you are new to the resolution-writing process, CMS leadership is happy to mentor you on using this powerful advocacy tool effectively. To learn more, please call 312-670-2550.

Illinois State Medical Society Delegates

Who Says there isn’t power in numbers? CMS is always extremely well-represented at the annual ISMS House of Delegates meeting and, is therefore, quite effective at making our voices heard. Here’s a listing of your colleagues who advocated on your behalf at the 2016 ISMS House of Delegates:

Delegates

Lia A. Arber, MD
Smitha Arekapudi, MD
Bapu P. Arekapudi, MD
Christine P. Bishop, MD
Ajay K. Chauhan, DO
Desiree Conrad, Student
Jacquelyne P. Corey, MD
Amy J. Derick, MD

Peter E. Eupierre, MD
Jere Freidheim, MD
Dennis L. Galinsky, MD
Richard A. Geline, MD
Linda F. Gruenberg, DO
Michael A. Hanak, MD
Susan B. Kern, MD
Norman V. Kohn, MD
Jerrold B. Leikin, MD
Scott M. Leikin, DO
Mark Looman, Student
Niva M. Lubin-Johnson, MD
Mason D. Marcus, Student
David W. Miller, MD
Vemuri S. Murthy, MD
Peter Orris, MD
David J. Palmer, MD
Robert C. Parker, Jr., MD
Ajanta Patel, MD

Jennifer R. Pyle, MD
Erin Schwab, MD
Shikhar H. Shah, Student
Tina R. Shah, MD
Christiana Shoushtari, Student
Kenneth L. Soyemi, MD
M. LeRoy Sprang, MD
Anthony J. Stephens, MD
Anne G. Szpinodor, MD
William N. Werner, MD
John A. Wiley, MD
Anna Zelivianskaia, Student

Alternate Delegates

Edith L. Graham, Student
Anne M. Langguth, MD
Joseph B. Lee, MD
Arden Plumb, Student
Learn how to analyze and advise on Stark Law issues with *What is Stark Law?*

**TOPICS INCLUDE:**

- An overview of the statute itself
- Regulations, specifically the regulatory exceptions, and the terms of the exceptions
- The source of interpretations of the Stark Law, including key cases and advisory opinions
- An overview of enforcement mechanisms and consequences for violations of Stark
- A list of resources to further assist attorneys as they research and analyze Stark issues

This book is a must have for any individual working with healthcare entities needing a general introduction to the statute and regulations governing financial relationships between healthcare entities.

**Product Code:** 5630122  
2014, 66 pages, 6” x 9” paperback  
**Editor and Authors:** Donald H. Romano, Jonathan E. Anderman, Matthew R. Fisher  
$49.95 / $35.95 for ABA Health Law Section Members

Go to [www.shopABA.org](http://www.shopABA.org) to order, or phone 1-800-285-2221
MEMBER BENEFITS

Calendar of Events

JUNE

9-10 Physician Legal Issues Conference 2016
Sponsored by the Chicago Medical Society and American Bar Association’s Health Law Section. Description: When confronted with aggressive hospital systems, lower reimbursement, and daily practice challenges, physicians are learning to adapt in very innovative ways. This program offers physicians, attorneys and their administrative partners an opportunity to hear how these issues are being addressed by physicians and how physicians can succeed at maintaining viable medical practices that offer quality services at their core. Participants will have access to national speakers and will be educated on key issues affecting employer and hospital relationships, business and industry responses to payer consolidation and market control, and every day “survival” techniques in hospital and private practice settings. Location: Palmer House Hilton, Chicago. For information, please visit: www.cmsdocs.org or contact Rachel 312-670-2550, ext. 338, or rburns@cmsdocs.org.

11-15 AMA House of Delegates & Annual Meeting
CMS actively participates in the AMA’s policymaking meetings, advocating for members and their patients. Resolutions adopted at the CMS governing Council frequently travel to the Illinois State Medical Society, where they are implemented, before ultimately reaching the AMA. CMS delegates to the AMA may submit a resolution directly to the AMA House for consideration and support. Physicians are encouraged to exercise this membership privilege, ensuring their voice is heard at the highest levels of organized medicine and beyond. Location: Hyatt Regency Hotel, Chicago. For information, go to www.ama-assn.org.

15 CMS Executive Committee Meeting
Meets once a month to plan Council meeting agendas; conduct business between quarterly Council meetings; and coordinate Council and Board functions. 8:00-9:00 a.m. Location: CMS Building, 33 W. Grand Ave., Chicago. For information, contact Ruby 312-670-2550, ext. 344; or rbahena@cmsdocs.org.

15 CMS Board of Trustees
Meets every other month to make financial decisions on behalf of the Society. 9:00-10:00 p.m. Location: CMS Building, 33 W. Grand Ave., Chicago. For information, contact Ruby 312-670-2550, ext. 344; or rbahena@cmsdocs.org.

17 Book signing by CMS/ISMS member Dr. Saul Weiner
Published by Oxford University Press in 2016, Dr. Saul Weiner’s book, “Listening for What Matters: Avoiding Contextual Errors in Health Care” describes a line of research and quality improvement initiatives that his team has pursued for years to address the challenge of physicians adapting care to patients’ individual needs and circumstances. The book is co-authored with Alan Schwartz, PhD, editor of the journal Medical Decision Making. The book should be of broad interest to those interested in health outcomes, patient centered care, medical education, and performance improvement. 11 a.m. - 1:30 p.m., Union League Club Crystal Room, 65 W. Jackson Blvd, Chicago.

Patient Balances
Get Control with PBC Advisors’ Patient Collection Improvement Program

Action Plan:
• Update Financial Policies
• Revise Eligibility and Benefits Investigation Workflows
• Develop Pre-Service Estimate Tools and Workflows
• Train Staff to Professionally Collect from Patients
• Develop Collection Agency Measurements and Monitoring
• Develop “Practice Dashboard” for Ongoing Monitoring

Outcome:
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Welcome, New Members!

The Chicago Medical Society welcomes its newest members. We are now 9 voices stronger!

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Victoria L. Konold, MD
Alex Neuman, DO
Samer R. Rajjoub, MD
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District 6
David A. Ansell, MD
Catherine C. Cheng, MD
Ryan M. Lustenberger, MD
Kristen I. Padilla, DO
Dr. Robert A. Barish couldn’t be happier in assuming the new role of vice chancellor for health affairs at the University of Illinois at Chicago. “It’s an honor to lead such a noble institution, aligning our academic mission with our healthcare delivery system; we’re increasing our clinical care, research and community service,” he says.

He was among a select group of individuals invited to become a NASA astronaut candidate, and in 2005 he helped lead a medical regiment to deliver emergency care to more than 6,000 Hurricane Katrina victims on the Gulf Coast. And now Robert A. Barish, MD, MBA, has moved into the role of vice chancellor for health affairs at the University of Illinois at Chicago, a position he accepted last Jan. 1.

The title belies the enormity of the restructured position; he oversees: the university’s 495-bed tertiary care hospital and clinics, 13 federally qualified health centers located in many of Chicago’s most medically underserved communities, as well as UIC’s seven health sciences colleges and their respective regional campuses, including the College of Medicine—the largest medical school in the United States, with one of the most diverse student bodies.

And he couldn’t be happier. “It’s an honor to lead such a noble institution, aligning our academic mission with our healthcare delivery system; we’re increasing our clinical care, research and community service,” Dr. Barish says. “We can now better address key health needs in the state, especially in our underserved communities.”

A Restructured Role
Speaking to the UIC Alumni Magazine earlier this year, Dr. Barish explained how his new role alters the structure and character of UIC’s health care delivery system. “Under previous protocols, a vice president for health affairs reported directly to the university president while assuming responsibility for its health care delivery system, including hospitals and clinics.” He says that as vice chancellor for health affairs, he reports to UIC Chancellor Michael Amiridis, and not only oversees patient care, but also academic and research enterprises. “Integrating and aligning those endeavors promotes potential synergies, helping to ensure success of the entire enterprise.”

Career Highlights
After earning his medical degree from New York Medical College in 1979, Dr. Robert Barish interrupted his residency training for one year to provide medical treatment to refugees at camps along the Thai-Cambodian border and in Somalia. He completed an internal medicine residency at New York’s Saint Vincent’s Hospital and Medical Center in 1983 and an emergency medicine residency at Georgetown University Medical Center in 1985. He is a member of Alpha Omega Alpha Medical Honor Society, a fellow of the American College of Emergency Physicians, and a fellow of the American College of Physicians.
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