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The ACA: Pros, Cons, Public Ire

The Affordable Care Act (ACA) continues to generate strong opinion. Chicago Medicine’s goal has been to accurately report on the law, with balanced and useful information for our 5,000-plus physician-subscribers. The law aims to address rising health care costs and significant coverage gaps in states like Illinois where an estimated 13% of the population, or 1.7 million people, were uninsured.

The disastrous rollout of the ACA on Oct. 1, 2013, includes a dysfunctional Healthcare.gov website and dismal initial enrollment numbers. By the final enrollment date of April 19, 2014, over eight million Americans had selected a marketplace plan, according to the Department of Health and Human Services. But there are important caveats to this enrollment number, since there are likely significant numbers of duplicate enrollments. Moreover, choosing a marketplace plan is not synonymous with paying the premium and having insurance.

The initial rollout was also marred by the phase-out of existing individual plans that did not meet the minimal ACA coverage requirements. Some plans have now been grandfathered in, and some affected individuals have found replacement exchange insurance. For patients, the ACA offers popular benefits. The law eliminates pre-existing diagnosis exclusions and lifetime limits, sets minimal standards for all insurance products, and allows young people to remain on their parents’ plans until age 26.

On the physician side, several ACA provisions affect office management policies:

- **Cost-sharing mechanisms.** A Chicago Tribune analysis in October of the lowest-price Cook County plans found that 21 out of 22 had annual deductibles of at least $4,000 for individuals and $8,000 for families. With the sharp increase in high-deductible plans, offices must be proactive at collecting co-pays and deductibles at the time of examination.

- **Coverage gaps.** Participating insurers must grant a 90-day grace period to pay delinquent premiums, if the individuals are subsidized and have paid at least one premium. After 90 days of delinquency, the insurer can terminate coverage. The insurer is responsible for charges in the first 30 days. But in the 30-90 day period, physicians are not paid for services by the insurer and must collect from patients.

- **Narrow networks.** Insurers insist that smaller panels with lower reimbursement are a prerequisite for cost control. The industry uses the example of Medicare Advantage, contending that the trend toward smaller panels was already in progress. This is reminiscent of the early 1990s when HMOs pushed to restrict physician panels, raising the public’s ire.

- **Rise of ACOs.** At least 360 Accountable Care Organizations (ACOs) exist nationwide, serving 5.3 million Medicare beneficiaries. Chicago Medicine (May 2014) documented the ACO rollout in Cook County and the programs at Advocate Health Care and Presence Health. Individual physicians need to evaluate the opportunities for their own practices to participate in ACOs.

On a personal note, it has been a privilege to serve this past year as your CMS representative. I was repeatedly amazed at how warmly CMS representatives were greeted in hospital boardrooms, Springfield, and even in Washington, DC. CMS members can be proud that our 164-year-old Society is so highly regarded by the public and elected officials. I am also confident that incoming President Kenneth G. Busch, MD, will continue his tireless service to CMS in the areas of public health, education, and advocacy.

Robert W. Panton, MD
President, Chicago Medical Society
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On April 9, the Centers for Medicare and Medicaid Services (CMS) publicly released physicians' Medicare claims data, including billed charges and total payments. Although most people believe that transparency in health care is important, the way in which this data has been released has a number of organizations concerned. Here are some of the concerns expressed by organizations such as the American Medical Association and the American Academy of Family Physicians:

- Errors in the data. At this time, there is no way for a physician to correct errors.
- Care quality cannot be assessed from this information. The data focuses only on payment and use of services without any information about the quality of care provided.
- The number of services reported could be misleading. Numerous non-physician providers are allowed to bill for services under a physician's NPI; therefore, the data may not properly convey who performed the services and may give an inflated view.
- Payment versus cost. Since most payers have a fixed fee schedule in place for paying physicians, the payment data does not accurately portray physician compensation nor does it take into consideration the many changes mid-year in coding rules and different billing rules based on local coverage determinations, which can also skew the data.
- The data does not differentiate subspecialty care. The data collected categorizes physicians into those subspecialties that Medicare has listed. This does not take into consideration those physicians who provide subspecialty care and therefore they cannot be compared to other physicians listed under the same specialty.

How to Handle Patient Questions

- Inform patients that Medicare payment is not the same as a physician's personal income. Business expenses need to be subtracted from these amounts. The average breakdown, according to the CMS Medical Economic Index, places about half of payments in one of many expense categories it takes to run a practice. Additionally, this data does not differentiate the reimbursement of drugs, which in many cases, Medicare reimburses just for cost. Some physicians use high-cost drugs, which inflate the payment.
- The number of services provided by physicians may not be an accurate measure of what is actually performed. Some physicians who provide services may not even be included since some physicians provide their services under a group NPI number and not their own. Conversely, some physicians may have an over-inflated number of services since they have numerous non-physician providers delivering services under their NPI.
- This data does not include any measure of quality. The focus is on the number of services and payments, which does not reflect any information on outcomes or comparisons to non-Medicare patients.
- Finally, the data only shows a small part of the whole picture. The data does not include claims for patients covered by commercial insurance, Medicaid or Medicare Advantage.

This article is provided courtesy of Professional Business Consultants, www.pbcgroup.com.
Physician Suicide
A growing problem By Daniel H. Angres, MD

Not long ago, a national conference on physician health reported that the substantial increase in physician burnout appears to be a major contributor to suicide attempts and completed acts in our colleagues. This underscores the importance of addressing burnout as well as having an open dialogue about these issues within our profession. Feelings of shame, isolation and inadequacy are the bedrock of self-destructive behaviors. We need to support each other like never before.

Dr. Angres is medical director of Presence Behavioral Health. Inquiries about the CMS Physician Wellness Committee or confidential questions should be sent to Dr. Angres at angres@presencehealth.org.

QUICK TIP

IN ANY PHYSICIAN practice, it is all too common for schedules to slip, either because a patient took more time than anticipated or an emergency arose causing your schedule to derail. When that happens, someone on your staff should inform patients in the waiting room about the delay. Staff should offer to reschedule any patients who are inconvenienced. Be sure to apologize to the patients and also thank them for waiting. Remind them that their patronage is always appreciated.

I know you’re busy, but we were just served suit papers on a patient.
Send me the number of my malpractice insurance carrier.

Who would you be without your reputation?
Make sure your reputation is protected with medical malpractice insurance coverage from PSIC.
A Failing Grade
New report finds that Cook County’s air quality is worsening

HE AMERICAN Lung Association’s “State of the Air 2014” report released in late April shows that Cook County has seen no change in year-round particle pollution (soot) levels compared to the 2013 report. This is in spite of a trend seen across the nation of lower particle pollution levels. Cook County has also experienced more unhealthy days when short-term particle pollution has reached unhealthy levels. Metropolitan Chicago ranked as the 14th-most polluted city in the nation for short-term particle pollution, 20th-most polluted for annual particle pollution, and 20th-most ozone polluted, all worse rankings than last year’s report.

Although the air in Chicago is cleaner than when the first report came out 15 years ago, much work remains to be done. Looking at air quality in 2010, 2011 and 2012, Chicago’s air pollution declination shows up in Cook County, which failed to improve its year-round particle pollution, receiving a failing grade. Cook County received an “F” grade for short-term particle pollution, because of too many days of unhealthy particle levels. Particle pollution levels can spike dangerously for hours to weeks on end (short-term) or remain at unhealthy average levels every day (year-round). Particle pollution can penetrate deep into the lungs and even into the bloodstream, leading to premature deaths, asthma attacks and heart attacks, as well as lung cancer.

The report also found that Chicago’s ozone levels worsened, resulting in an “F” grade in Cook County where the peak levels from the metro area are monitored. Ozone is the most widespread air pollutant, created by the reaction of sunlight on emissions from vehicles and other sources. When ozone is inhaled, it irritates the lungs and can cause immediate health problems, which may continue days later. Ozone can cause wheezing, coughing, asthma attacks and premature death. Unfortunately, reducing ozone pollution is particularly challenging because warmer temperatures increase the risk, and climate change sets the stage for higher ozone levels in the future.

Metropolitan Chicago ranked as the 14th-most polluted city in the nation for short-term particle pollution.”

But Chicago is not alone. Nearly half of Americans—more than 147 million—live in counties where ozone or particle pollution levels make the air unhealthy to breathe, an increase from last year’s report. But on the bright side, while the report shows that the nation’s air quality worsened in 2010-2012, overall quality remains much higher than just a decade ago. Data from the Environmental Protection Agency shows that since 1970, air has gotten cleaner while the population, the economy, energy use and miles driven increased greatly.

As of press time (June 2), the Obama administration had just released a proposal to reduce carbon dioxide emissions from existing power plants. Coal-fired power plants account for a large share of the nation’s heat-trapping carbon emissions. The proposed rules, which limit pollutants that contribute to soot, acid rain and ozone, form a key component of the administration’s plan to fight climate change. To view the ALA report, visit www.stateoftheair.org.

Stemming Coal’s Deadly Toll

THE AMERICAN Lung Association calls for all states to comply with healthy air standards to protect citizens from pollution and new threats caused by rising temperatures. The Chicago Medical Society is active on this front too. As a partner in Chicago’s Clean Power Coalition, CMS testified at City Hall on behalf of an ordinance to require coal-fired power plants to reduce their particulate and carbon dioxide emissions.

The Clean Power Coalition teamed with Mayor Emanuel to negotiate an agreement with Midwest Generation, LLC, a subsidiary of Edison International, to close Chicago’s last two coal-fired plants and largest source of air pollution. Under an expedited timetable, both the Fisk generating station in Pilsen, and the Crawford coal plant, in the Little Village neighborhood, shut down in 2012. Together the plants emitted thousands of tons of sulfur dioxide and nitrogen oxides each year, which led to the formation of ozone smog and fine particle pollution.

According to a 2010 Clean Air Task Force report, pollution from power plants is responsible for an average of 347 deaths, 264 hospital admissions and 584 heart attacks per year in the metropolitan Chicago area alone. In exchange for retiring the plants, Mayor Emanuel agreed to pull the proposed ordinance, while other groups agreed to withdraw from a federal lawsuit against the company. Also in 2012, Dominion Inc.’s State Line coal power plant, which operated mere feet from Chicago city limits in northwest Indiana, was permanently closed.

Four other coal power plants still operate in the suburbs of Chicago in Lake and Will Counties and continue to degrade air quality in the region. These plants were built before the Clean Air Act was passed in 1970, and have avoided installing necessary modern pollution controls for decades. Many more large coal power plants still operate in Illinois outside, but upwind of, the Chicago area, according to the Respiratory Health Association of Metropolitan Chicago, a founding member of the Clean Power Coalition.
Gender Differences in Alzheimer’s Disease

Women are more likely to fear developing the condition as they age

By Neelum T. Aggarwal, MD

The relationship between gender and medical disease is a growing area of interest among clinicians and researchers alike. Data from many countries suggest that men die younger, while women bear a heavier burden of chronic illness. Studies also suggest that men and women behave very differently in their use of health care services. They have different thoughts and beliefs about disease, and perceive their risk of developing disease differently. This latter theme—gender differences in perceived risk—has also been examined by researchers in all disciplines using various modalities.

How the sexes perceive their risk of developing Alzheimer’s disease is one emerging area of interest. Studies have shown that women are indeed at greater risk of developing Alzheimer’s disease.

An Israeli study in 2012 documented these potential differences in a telephone survey of people age 18 and up. Assessing levels of concern about developing Alzheimer’s disease, researchers made 1,292 phone calls using random digit dialing. Of the 632 participants who gave complete interviews (67.5%), the majority were female (52.5%), with a mean age of 45 (age range of 18-88) and average education of 14 years (range of years 0-28). Most were married (70%) and a quarter (25%) reported having a relative with Alzheimer’s disease.

One question assessed awareness: “Did you ever hear about AD?” A negative answer was rated as 0 and a positive answer was 1. Questions about susceptibility, fear or worry about developing AD, were assessed with separate questions, and answers and were based on the Likert scale (1 = not at all likely to 5 = very likely). Socio-demographic variables included gender, age, education, marital status and ethnicity.

The study found that men and women had similar levels of awareness, but significant differences in mood-related symptoms, such as perceived susceptibility, worry, and fear of developing Alzheimer’s disease. Moderate to high overall perceived susceptibility was observed in 12% of men, compared to 18% of women. The number of women reporting these symptoms was consistently higher and the differences were statistically significant at p<0.001).

The predictors of belief and mood observed in this study tend to vary widely, except for perceived disease susceptibility. Higher perceived susceptibility was related to familiarity with someone who had Alzheimer’s disease, less education and higher age.

Susceptibility Key to Changing Behavior?
What do these findings potentially mean for education and awareness campaigns internationally and here in the United States? Tailoring Alzheimer’s disease education to focus on susceptibility could be more effective in changing behavior. Research in health behavior has shown that perceived “vulnerability” may influence behavior more than simple education.

Because of our increasingly diverse population, research in this area must include multiethnic communities to examine potential racial and ethnic differences in disease perception along with sex and gender differences.

Studies utilizing telephone interviews have already noted differences among multiethnic populations in their perceptions of Alzheimer’s disease. African-Americans and Hispanic respondents were more likely to believe that Alzheimer’s disease is a normal part of aging. However, more research is needed in these cohorts, on sex and gender along with race and ethnicity and their relationship to disease incidence. Such research will provide valuable information for clinician researchers in the field of aging and dementia, helping us to provide the best possible care in a culturally specific and sensitive manner, while also being aware of existing sex and gender differences.

For a list of references, please contact esidney@cmsdocs.org.

Dr. Aggarwal is co-leader of the Rush Alzheimer’s Disease Clinical Core, a founder of Women Against Alzheimer’s Disease, and chief diversity officer of the American Medical Women’s Association. She can be emailed at DiversityChief@amwa-doc.org.
UPDATE: Medical Cannabis

State regulatory bodies release proposed regulations for public comment and review

By Jonathan Loiterman, JD

ILLINOIS’ Compassionate Use of Medical Cannabis Pilot Program Act provides a framework for patients to acquire and use medical cannabis produced exclusively by licensed cultivation centers and sold by licensed dispensaries (see May 2014 article). Illinois regulatory bodies are moving forward with drafting regulations governing the registration and licensing processes for patients, dispensaries, and cultivation centers.

On April 18, the Illinois Department of Public Health (IDPH), the Illinois Department of Financial and Professional Regulation (IDFPR), the Department of Agriculture (DoA), and the Department of Revenue each submitted proposed regulations for public comment and review by the Joint Committee on Administrative Rules (JCAR). You can find the new regulations at http://mcpp.illinois.gov.

The JCAR and public comment process is expected to take between 90-120 days, after which IDPH, IDFPR, and DoA will provide final details about when and how patients, dispensaries, and cultivation centers can apply for registration or licensing under the Act. Any possession, use, distribution or sale of cannabis remains prohibited under Illinois law until these regulations are finalized and the necessary registrations and/or licenses required under the Act have been issued. Cannabis will remain illegal under federal law.

The following are highlights from the proposed regulations submitted to JCAR. The regulatory provisions cited below may be subject to change.

Physicians
• Written certifications must include: patient identifying information; physician identifying information, including the DEA registration number; the length of time the physician has provided care to the patient; the patient’s qualifying condition; a statement certifying the existence of a bona-fide physician-patient relationship, including an in-person physical examination; a review of the patient’s medical history (12 months of records from other treating physicians); and an explanation of the potential risks and benefits of cannabis use.
• Physicians may not serve on the board of directors or as an employee of a cultivation center regardless of whether the physician has or intends to certify patients under the Act.
• Physicians may have a financial interest in a medical cannabis dispensary or cultivation center provided they do not certify patients under the Act.
• Physicians may not advertise on the premises of cannabis businesses or have any type of referral arrangement.
• Physicians are required to maintain records on several specified items for cannabis patients, including: visit dates; current medical history; description of the patient’s current medical condition; physical examination results; a treatment plan; informed consent; diagnosis and treatment rendered; a list of all drugs prescribed; radiographs and other diagnostic test; financial and billing records; identification of physicians or assistive personnel providing services; and laboratory results.
• Physicians are not required to maintain a separate record of qualifying information for their cannabis patients.

Patients
• The process for adding new qualifying medical conditions through IDPH now includes a Medical Cannabis Advisory Board of 15, including a cannabis patient advocate or caregiver, two nurses or nurse practitioners, three registered qualifying patients, and nine physicians, including one specialist each in neurology, pain management, oncology, psychiatry, infectious disease, family medicine, general primary care, medical ethics, and pharmacy. The board will convene twice per year, but the director of IDPH makes final decisions about additional qualifying conditions.
• In 2014, patients with last names beginning with the letters A through L will be able to submit applications from Sept. 1 through Oct. 31. Patients with names beginning with the letters M through Z will be able to submit applications between Nov. 1 and Dec. 31.
• Beginning in 2015, IDPH will accept patient applications year round.
• $100 registration fee for eligible patients; $50 for patients on Social Security; $25 for caregivers.
• Patients will pay a 1% tax on cannabis purchases.
• Registered patients are no longer prohibited from holding a firearm concealed carry license.
• Patients have an independent duty to report to IDPH if the patient ceases to qualify or changes his or her designated caregiver, subject to a penalty of up to $150.
• Although felony drug convictions generally disqualify a patient from receiving a registration, a patient cannot be denied on the basis of a conviction related to medical use of cannabis and the termination of the last sentence was 10 or more years prior to the application.
• The approval or denial of applications for registration and petitions for the inclusion of additional qualifying conditions are subject to judicial review.

Dispensaries
• There will be up to 22 dispensaries outside of the Chicago metropolitan area.
• There will be up to 14 dispensaries within the Chicago metropolitan area but outside Cook County.
• There will be 11 dispensaries outside the city of Chicago but inside Cook County.
• There will be 13 dispensaries in the City of Chicago.
• All dispensaries are subject to applicable zoning rules.

Jonathan Loiterman is a senior associate at Lowis & Gellen, LLP.
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The 340B Drug Discount Program

Controversy

Major changes are expected this year  

By Ellyn L. Sternfield, JD

The year 2014 is expected to bring major changes to the 340B Drug Discount Program. Through this program, pharmaceutical manufacturers discount the cost of drugs to registered safety net or “covered entity” providers of outpatient services. To understand where the program is going, it helps to know where it has been.

Understanding the 340B Drug Program

Named after the enacting statute, the 340B Program was created by legislation in 1992 and is administered by the federal Health Resources and Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS). Drug manufacturers must participate in the 340B Program as a condition of Medicaid coverage for their products.

The discounted price of drugs to covered entity providers of outpatient services is known as the “ceiling price.” This price is calculated based on confidential pricing data the manufacturer provides to the federal government. Covered entities must ensure that 340B drugs are used solely for 340B patients and not diverted for other uses; entities must prevent “duplicate discounts” by ensuring that 340B drugs are exempt from Medicaid rebate invoicing. The 340B Program has grown tremendously in recent years, and that growth has been accompanied by criticism from multiple sources. Much of the criticism stems from disagreement over the 340B Program’s purpose.

Pharmaceutical manufacturers and other industry groups assert that the 340B Program was the natural outgrowth of the 1990 Medicaid Drug Rebate Program, through which manufacturers pay rebates to states based on their reported “best price” for drugs reimbursed by Medicaid. Since “best price” was defined to include all discounts, manufacturers were effectively discouraged from discounting drugs as a form of charity for safety net providers. Through the 340B Program, the mandatory discounts to qualified safety net providers are exempt from “best price” reporting for Medicaid rebate purposes. Manufacturers question whether 340B drugs are now being provided for non-charity purposes and whether inadequate oversight means they are paying duplicate discounts in the form of Medicaid rebates for 340B drugs.

Hospitals, safety net clinics, and other institutional providers assert that the 340B Program was created to allow safety net providers to access deeply discounted drugs in order to stretch limited resources and treat as many needy patients as possible. They bristle at attempts to limit access to 340B drugs, arguing that the ability to provide 340B drugs to insured patients and obtain full insurance reimbursement allows manufacturers to increase services for the indigent, consistent with the underlying purpose of the 340B Program. The divide between manufacturers and institutional providers frames much of the current controversy.

What Critics Say About the 340B Program

In a September 2011 report, the Government Accountability Office (GAO) noted the explosive growth in the number of covered entities qualified to dispense 340B drugs, in the use of those drugs, and in the profits generated by insurance coverage of 340B drugs. The GAO was critical of HRSA’s lackluster oversight of the 340B Program and its use of a vague definition of who qualified as a 340B “patient.”

Congress has also questioned the operations of HRSA and the 340B Program on issues such as access to 340B drugs and pricing, HRSA audit and oversight activity, and use of 340B profits. Trade associations have jockeyed to issue reports on the problems or successes of the 340B Program, depending on their view of its purpose.

The 340B Program in 2014

This year is expected to bring major changes to the 340B Program. So far, covered entities and drug manufacturers have already seen increased HRSA audit activity and imposition of sanctions; HHS-OIG stepping up its oversight and criticism; written arguments in a lawsuit over 340B orphan drug rules; and increased funding for HRSA oversight. But it is HRSA’s planned publication of regulations in June 2014 that may have the greatest impact. Here are details:

HRSA Audit Activity. Since the publication of the GAO report, HRSA has increased its oversight and now requires covered entities to be recertified. HRSA has also intensified its audit activities, with the goal of conducting 200 compliance audits each year. While it is not clear how many audits have been completed to date, HRSA does periodically publish audit results on its website at www.hrsa.gov. Those reports generally identify compliance violations in up to two-thirds of the completed audits. The most common findings involved...
drug diversion or dispensing of 340B drugs to a non-patient or inpatient; duplicate discounts or billing of the drug to Medicaid without protections against invoicing for Medicaid drug rebates; and database errors in the listing of related entities or contract pharmacies. Before January 2014, resulting sanctions for those violations were always reported as “pending.”

In January 2014, HRSA issued its report on finalized 2012 audits and for the first time indicated it had imposed some sanctions. For about half of the audited entities with an adverse finding involving drug diversion, a sanction of “repayment to manufacturer” is listed. No other monetary consequences have been reported. For the audit’s other adverse findings, HRSA lists the sanctions as “pending.”

**HHS-OIG Actions.** In its 2014 Work Plan, HHS’ Office of Inspector General (OIG) announced it will conduct three reviews of the 340B Program, examining:

- The extent to which HRSA and 340B covered entities oversee compliance by 340B contract pharmacies.
- The extent to which HRSA has implemented prior OIG recommendations on 340B covered entities’ access to 340B ceiling prices.
- Whether changes in practice or procedure might allow Medicare Part B to receive the benefit of 340B discounts when reimbursing for 340B drugs.

Within days of the Work Plan’s release, the OIG issued its first report.

In “Contract Pharmacy Arrangements in the 340B Program,” the OIG reported that two compliance problems highlighted in HRSA audits—diversion of 340B drugs to non-patients and duplicate discounts due to failure to appropriately track Medicaid billings—are exacerbated by the use of 340B contract pharmacies. The OIG found that contract pharmacies use varying and inconsistent methods to determine 340B patient eligibility because of “a lack of clarity” in HRSA’s definition of a patient. The report also found a lack of adequate processes to avoid duplicate discounts in Medicaid, especially in Medicaid managed care. While HRSA has issued guidance on oversight of contract pharmacies, the OIG found that most covered entities do not conduct the oversight recommended by HRSA.

Given the ongoing dispute over the 340B Program’s purpose, one other finding was telling: the OIG found that many covered entities do not offer 340B prices to uninsured patients through contract pharmacy arrangements. This may prove problematic to those 340B Program defenders who argue that its very purpose is to increase covered entities’ ability to provide services like prescription drugs to the uninsured.

**Orphan Drug Rule Lawsuit.** In July 2013, HRSA issued regulations implementing a Congressional directive that excludes orphan drugs from 340B pricing. Under the regulations, the orphan drug exception applies only to limited types of 340B covered entities and applies only if the drug at issue is being used for its orphan-approved purpose, leaving open the argument that 340B pricing is available if the drug at issue is prescribed for another purpose. The Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit to enjoin enforcement of the new rule, arguing that HRSA was not authorized to issue rules interpreting the legislatively adopted orphan drug exception. Briefing on that case closed with parties on both sides filing written arguments. A ruling is expected in coming months. A decision that HRSA lacked the authority to adopt rules interpreting the law may well impact HRSA’s future rulemaking on the 340B Program.

**Increased Funding for HRSA.** The Omnibus Budget Act funding of government activities through September 2014 more than doubled the budget for HRSA’s Office of Pharmacy Affairs, from $4.4 million to $10.2 million. President Obama’s proposed federal budget for 2015 calls for $17 million in HRSA funding. These increases are designated for program integrity efforts. Just what those integrity efforts involve remains to be seen.

**HRSA Planned Rulemaking.** On Jan. 9, HRSA served notice of major changes to come. HRSA is currently working to formalize existing guidance through regulation to cover aspects of the 340B Program. The regulation under development will address the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities. This proposed regulation will be open for public comment by June 2014.

**In Conclusion**

On April 9, 2014, the Office of Management and Budget acknowledged that HRSA had forwarded proposed regulations governing the operations of the 340B Drug Pricing Program for review. Barring unforeseen consequences, the government appears on track to publish rules in June 2014. But establishing a full regulatory structure for the 340B Program may be difficult in the absence of a clearly defined objective for the Program. It also remains to be seen whether HRSA will use these rules to finally settle the dispute over the 340B Program’s purpose.

Ellyn L. Sternfield, JD, is of counsel to the international law firm of Mintz Levin, working in the firm’s Washington, DC, office. She has more than 30 years of legal experience, with an extensive background in the field of government health care enforcement. Ms. Sternfield frequently speaks and writes on health care fraud and abuse matters, and is a contributor to the Mintz Levin Health Law & Policy Matters blog.
The Sunshine Act: A Roadmap for Compliance

Tips for determining fair market value By Jen Johnson, JD, CFA, MBA

STARTING Feb. 18, 2014, manufacturers and group purchasing organizations in the life sciences industry could begin reporting to the Centers for Medicare and Medicaid Services (CMS) payments or other transfers of value to physicians or academic medical centers (AMCs). This reporting requirement, established in the Affordable Care Act, is known as the Sunshine Act or the Open Payments program. A major goal of the program is to increase transparency by making information about certain payments to physicians and AMCs available on a searchable public website.

These compensation arrangements, which may include payments to providers for administrative as well as clinical services, must be set at Fair Market Value (FMV). Various laws and regulatory guidance, including The Anti-Kickback Statute, Stark Act, False Claims Act, and the Office of Inspector General all reference the importance of establishing FMV for physician payments. With public disclosure, the possibility that some payments will not be viewed as FMV increases, potentially triggering scrutiny from the government or whistleblowers.

For the life sciences industry, which has the overwhelming task of gathering compensation data, an even larger challenge looms: defending the data. Information about payments must be disclosed, and so questions related to the amount of compensation paid for certain services are likely to arise, from industry, government, and the public. All parties involved must ensure that compensation is at FMV. This article discusses methodologies used to set FMV payment for physician services and provides guidelines to assist organizations in documenting a defensible compensation arrangement.

FMV Basics

Within the life sciences industry, companies may use several arrangements to compensate physicians or AMCs for their clinical expertise. The referral relationship between a life sciences company and an AMC is similar to that between physicians and hospitals. Since the latter has historically required strict adherence to the FMV standard, consulting the previous regulatory guidance on acceptable methodologies is advised.

A glossary of terms jointly developed by various national appraisal organizations defines FMV as:

• The price, expressed in terms of cash equivalents, at which a 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 to sell, and when both have reasonable knowledge of the relevant facts.

Of note, the determination of FMV under health care regulations may not always be consistent with generally accepted appraisal standards. In fact, certain departures from standard appraisal practice may be required. Specifically, the methodology must not rely exclusively upon data points that are based on arrangements where parties were in a position to refer. For example, if a pharmaceutical company compensated a physician for consulting services at a certain hourly rate, this would not be adequate FMV documentation for another company to establish payments to the same physician; it is considered “tainted” because it is assumed that the first company likely receives referrals from the physician. This concept is well known throughout the health care valuation industry. Said another way, certain data should not be relied upon exclusively; the FMV process is expected to be thorough.

The following guidelines for establishing FMV compensation look at physician services in life sciences arrangements.

Determining FMV for Administrative Services

This category includes consulting, the administrative review and discussion of clinical trials, written abstracts and manuscripts, as well as speaking engagements. Here is the previous regulatory guidance on FMV for health care providers who deliver administrative services:

• A Fair Market Value hourly rate may be used to compensate health care providers for both administrative and clinical work, provided that the rate paid for clinical work is FMV for the clinical work performed and the rate paid for administrative work is FMV for the administrative work performed. The FMV of administrative services may differ from the FMV of clinical services.

Based on this guidance, one should note that administrative services may be valued differently than clinical services. It is important to understand the service being provided and the experience and qualifications required for their provision. Ideally, one would rely on compensation data for health care providers who are delivering the same services,
in the same specialty, with the same experience. However, this survey data may not be available.
One should also consider whether the data appears overstated in order to avoid relying on data that could be tainted by referral relationships. Thus, to establish FMV compensation, one should apply multiple valuation methodologies, such as referencing public survey data for physicians in similar roles, or conducting industry interviews and research.

Another data source may include compensation for physicians in clinical practice, assuming clinical expertise is required for the administrative role. For instance, if the administrative services require a physician with a particular specialty, clinical compensation survey data may be appropriate. However, relying solely on this data because it is the “opportunity cost” (what the physician would earn during surgery), may not provide defensible documentation alone, from a FMV standpoint.

Determining FMV for Clinical Services

Arrangements within the life sciences industry often require providers to perform clinical services. These services may include office visits, surgery or test interpretation. Of note, if an AMC or physician is receiving compensation for clinical services from the life sciences industry, it likely will not make sense for the AMC or physician to bill the patient for the same service. Specifically, it could appear that the physician is being paid twice if he or she is able to collect for the same service from a patient and from industry.

The following describes two methods for establishing FMV compensation for clinical services (assuming the physician cannot bill and collect from the patient).

• If the provider is delivering a service that has a relevant CPT code, the market reimbursement for that code, or a similar procedure, may be an acceptable compensation methodology. This amount would reflect what another willing buyer of the services would pay in the market, or FMV. Alternatively, if one is unable to link the procedure to a CPT code or market reimbursement, other methods may be relied upon. Most healthcare valuation firms rely on multiple objective salary surveys of clinical compensation by specialty. It is important to understand the experience of the health care provider, the complexity of the procedure, time required and other factors when using reported compensation data.

Compliance Checklist when Establishing FMV

In addition to appropriately determining FMV compensation, establishing internal policies for compensation is advised so that a consistent methodology is applied to all payment arrangements. Physician and AMC arrangements within the life sciences industry should follow these steps:

• Document time and understand services to be provided.
• Clearly understand the experience requirements.
• Clearly understand the subject health care provider's qualifications.
• Reference multiple, objective, and independently published salary surveys.
• Consider multiple valuation approaches.
• Understand that FMV of administrative services may differ from FMV of clinical services.
• Do not rely exclusively on survey data based on referral relationships.
• *Do not rely exclusively on opportunity costs.

Regulatory authorities may not only question the amount of payments, but also the reason for payments. A robust compliance program should provide safeguards against arrangements that do not make sound business sense. The following questions are closely tied to the FMV requirement and should be asked when reviewing arrangements between the life sciences industry and a provider (AMC or physician):

• Is there a legitimate need for the service?
• Did the appropriate department engage the physician consultants (not the marketing department)?
• Was the physician chosen based on his or her expertise in clinical practice?
• Are there a reasonable number of consultants available?
• Is there documentation showing that the services were actually provided?
• Is the physician consultant or AMC receiving additional benefits not tied to the payment (funding for a research trial or equipment post-trial)?

One cost-effective way to maintain compliance includes a table of hourly rates for various services based on expertise and required specialty. Another option may be to establish a conservative internal hourly rate for compensation, but when certain arrangements deviate from the internal threshold, the organization should seek a third-party FMV opinion.

The public reporting of AMC and physician compensation data is likely to trigger payment-related investigations, followed by documentation to show that compensation was set at fair market value.”

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How massive amounts of information are impacting health care

By Howard Wolinsky

IT’S CALLED BIG DATA. And big it is for big data may include a whole genome analysis or all electronic medical records in a physician practice, a health system, or an entire country. The idea in part is to collect data to tease out previously unobserved trends, such as predicting which patients—based on co-morbidities, stage of disease, age, you name it—are at high risk for a bad outcome and so merit special attention. Big data also may provide new information about a medication or therapy that affects the outcome of care.

Justin Starren, MD, PhD, chief of the Division of Health and Biomedical Informatics at the Northwestern University Feinberg School of Medicine, says informatics for the past 50 years has faced issues of having nearly more data than it can handle with existing tools. “In some ways big data isn’t new,” he says. “We’ve always been building tools to handle bigger and bigger data.”

But Dr. Starren, who trained in radiology and switched to informatics, says today’s informaticists define big data as the “three Vs:”

Volume = a lot of data.
Variability = complex data.
Velocity = data coming so fast that you can’t analyze it and react.

Some experts add a fourth V for veracity. “Or, the lack of veracity,” Dr. Starren says. “When you get so much data it tends to be noisy, so you don’t know if any individual piece of data is representing the truth, so you have to infer probabilistically across a lot of data points to get a sense of what’s true.”

Health care has latched on to big data big time—as has business, hard science and everyone else who deals with lots of numbers. Why health care? Why now? Will big data change your practice?

Torrents of Data

Big data is a hot topic now because of the move into EMRs spurred by the Obama Administration’s 2009 economic stimulus package. EMRs have made data collection possible as never before, says Dr. Starren. In addition, data storage is increasingly inexpensive, such as on data clouds, and there are new tools available to analyze the data.

Also, new torrents of data are becoming available from...
data-rich full genome scans and even from popular fitness devices, such as Fitbit and Jawbone, which have the potential to stream data about activity, pulse, sleep patterns and more, every minute of every day.

Robert Palmer, co-founder and CEO of Potentia Systems, a spinout from Washington University in St. Louis that creates software tools for analyzing health care, wellness, fitness and sports data, says any networked device that connects a patient to a doctor has the potential to create a fire hose of data for each patient. He gives the example of insertable cardiac monitoring systems designed to help quickly diagnose and treat irregular heartbeats that may be related to unexplained fatigue. Devices like this collect live feeds of heart rhythm data on a constant basis.

Palmer says his firm is gathering and analyzing such data. He thinks this potentially could change medical knowledge and practice. “Historically, we haven’t understood what variations there are in heart rhythm. But now that connected devices are uploading this data, we really need to come up with new rules around how we define atrial fibrillation. Healthy people may go in and out of rhythm at different points in the day, but since we weren’t monitoring this in the past, we were unaware of that.”

Physicians in the future may collect live feeds from fitness devices as well as medical devices. “The volume and the speed will be tremendous,” Palmer says. “Say you’re an internal medicine doctor. It’s not unusual for an internist to have 5,000 patients. What if there are 5,000 patients connected with one or two devices that are uploading 24/7?”

Speaking in March at the American Association for the Advancement of Science's annual meeting in Chicago, Robert Grossman, PhD, chief research informatics officer and director of the initiative in data intensive science at the University of Chicago Medicine, outlined the potential of big data. “If you have computing on this scale, you can ask questions that you might not ask otherwise,” he says. “In other fields, we ask ‘can we analyze the data each night so when we wake up in the morning we have the best available knowledge to make decisions that day?’ We don’t do that in biology, medicine, or health care. But what if we had enough computing power so that we could reanalyze all of the world’s tumor data each night? He says science has incorporated microscopes to look at small things and telescopes to look at things far away, but now needs “datascopes,” data centers where researchers can obtain the infrastructure and software to uncover clinically relevant therapy.

Defining Big Data

Big data, however, is still an ill-defined area, according to many experts. Andrey Rzhetsky, PhD, a mathematical biologist at the U of C, says, “Big data means completely different things to different people. What is big data for one set of people is small data for others. It's a buzzword, right?”

To him, big data means health records for whole countries, such as Denmark or the United States. From a practical viewpoint, he says the records for entire countries typically are for only one-third of the population. Still, that data can be extremely useful. For example, he says, you can ask questions about environmental influences or phenotypes like autism because you have information about each county obtained from insurance companies. “I’m specifically interested in deep connections between seemingly unrelated conditions, such as cancers and neurodevelopmental diseases or hormonal diseases and diseases of circulation,” says Dr. Rzhetsky.

He mines text written by clinicians in patient records, which puts notes into a computable form for studying millions of patients. He also works with insurance data. “Insurance data is not produced for studies,” he says. “It is just collected for billing. But there’s a lot of data, including genetic information, which is essentially the Holy Grail to finding the genetic determinants of complicated diseases such as diabetes, schizophrenia and bipolar disorder.”

Dr. Rzhetsky and his colleagues published a study last March in *PLOS Computational Biology* analyzing 100 million county-level medical records in the United States, revealing that autism is highly correlated and intellectual disabilities are borderline correlated with the incidence of genital malformations in newborn males. He says this suggests that pesticides may play a role...
in these conditions. In this way, big data is enabling new directions in public health and disease prevention. Dr. Rzhetsky also says this application of big data can reveal unusual, beneficial effects of existing medications and side effects that probably can be avoided.

**Snapshot: Diagnosing Diabetes**

Human geneticist Nancy Cox, PhD, has been using big data at the U of C to look at genetic components in common diseases, such as diabetes and asthma. “For diseases like type 1 and 2 diabetes, asthma, cardiovascular disease, or cancer, we are looking for the possibility that each DNA variant contributes just a small amount to a person's risk of developing these diseases,” she says. “But when we have information on millions of DNA variants, we can look at the information in aggregate to make much more accurate predictions about who is at risk for developing disease. This is a really interesting problem that may end up impacting medicine sooner rather than later.”

Dr. Cox is collaborating with researchers from the United States and Europe looking at genetic information related to type 2 diabetes, from 13,000 cases and controls, including more than 1,000 whole genetic scans. She says the research has shown that some patients have been misdiagnosed with type 1 diabetes, for example, rather than monogenic diabetes caused by a single gene mutation, including neonatal diabetes and maturity onset diabetes of the young. More than 20 genes have been linked with monogenic diabetes.

“It turns out that the way you treat those individuals might be quite different than how you would treat someone who actually has type 1 diabetes, which is usually with insulin injections,” she says. “When you tell families that the kids do not need to have shots after all, but can instead take pills and actually have better diabetes control, it’s certainly thrilling for the kids and of course it really alters the challenges the family has faced in terms of glycemic control.”

The discoveries in diabetes are “truly impacting patient care right now for a small minority of patients who have these particular rare forms of diabetes,” she adds. “But I think that in the near future we should be able to do this more and better. We will know in advance who is going to benefit from particular therapies rather than relying on trial and error. We won't have to guess at what might work and what might not. We'll have the evidence, based on their genetic profile, to make sound treatment decisions.”

**The Issue of Speed**

Cardiologist Elizabeth McNally, MD, PhD, has run the Cardiovascular Genetics Clinic at the U of C for 15 years, where genetic information is used regularly to diagnose inherited cardiac disease, especially cardiomyopathy. She says in recent years the field has been deluged with data from the growing use of next-generation sequencing for clinical diagnostics. She used to test for maybe 70 genes, but now she tests her patients’ whole genome. “Right now it is actually cheaper to do whole genomes than it is to do just parts of the genome,” Dr. McNally says.

In her practice, she looks at increasing numbers of genes in search of mutations that can help her decide whether to prescribe medication or to implant a device and to predict risk in relatives. “Community doctors are aware of this and are making good referrals,” she says, noting that specialists can help community physicians apply big data in care. “It’s really about awareness, to think about genetic diseases that affect adults and to make sure that family histories are being taken and genetic testing is being done where it should be,” she says.

Costs for full sequencing have dropped dramatically. Researchers are close to offering the $1,000 full genome. But it still takes months to analyze the data.

U of C researchers reported in the journal *Bioinformatics* in February that it was possible to analyze 240 full genomes in two days using the Beagle, the world’s fastest supercomputer devoted to life sciences based at Argonne National Laboratory. The Cray XE6 supercomputer is housed in the Theory and Computing Sciences building at Argonne. It was named after the *HMS Beagle*, the ship that carried Charles Darwin on his
famous scientific voyage in 1831. “This is a resource that can change patient management and, over time, add depth to our understanding of the genetic causes of risk and disease,” says Dr. McNally, who was a co-author of the study.

Lead author of the study, Megan Puckelwartz, PhD, a postdoctoral fellow in Dr. McNally’s laboratory, says the Beagle can process many genomes at the same time. “It converts whole genome sequencing, which has primarily been used as a research tool, into something that is immediately valuable for patient care,” she says.

**The Impact on Physicians**

Diego Klabjan, PhD, founding director of the master’s of science in analytics degree program at Northwestern’s McCormick School of Engineering and Management Sciences, says physicians ought to know about analytics in general, but don’t need training in big data techniques. “Big data is much more an IT/computer discipline. It’s not appropriate for most MDs, but they should know what big data can do.”

Northwestern is part of a consortium funded by National Human Genome Research Institute, the arm of the National Institutes of Health dealing with the genome and health, called the Electronic Medical Records and Genomics Project (eMERGE), which develops new methods for both research and patient care by combining EMRs with genomic data. For example, the project is looking at the genes that play a role in diabetes, looking for new associations. “By mining across millions of patients we’ll be able to say with a high level of confidence which genes play a role,” Dr. Starren says.

He says research historically has focused on the small number of people with a condition. “If you look at statistics, a huge fraction of modern statistics is all about how much we can generalize from that small number of people we’ve looked at to the whole population. With big data, instead of selecting, what we’re really doing is filtering. The idea is that you basically try to get all the data on everything of interest and filter it down to get the pieces you want.”

This methodology can also have a major impact on hospitals. Already, Dr. Klabjan says, big data is playing a role in keeping hospital readmissions to a minimum as the Accountable Care Act is implemented. “The data from patients, medical histories, and tests is taken into account, which is really big data,” he says.

Health care applications are another example of how physicians can use big data. “While they are predominantly offered by third-party companies and not hospitals,” says Dr. Klabjan, “they drastically affect hospitals. Patients can now find information and even treatment recommendations online by using apps,” he says. “These apps empower patients and facilitate the work of physicians. The majority of them use data from a variety of documents and web pages, and thus they use big data.”

**The Best and the Worst**

Yet while big data initially was greeted with enthusiasm, skeptics are now starting to raise questions. Back in 2009, big data hit public consciousness as media reported that Google Flu Trends accurately detected flu outbreaks based on flu-related queries in Google—besting the Centers for Disease Control and Prevention, which makes its forecasts based on flu surveillance reports from laboratories.

But subsequently Google Flu Trends didn’t do as well. It overestimated the prevalence of flu in the 2012-2013 season, as well as the actual levels of flu in 2011-2012, by more than 50%, according to a team of researchers reporting in *Science* in March. Additionally, from August 2011 to September 2013, Google Flu over-predicted the prevalence of flu in 100 out of 108 weeks, reported the article, “The Parable of Google Flu: Traps in Big Data Analysis.”

“Google Flu Trends is an amazing piece of engineering and a very useful tool, but it also illustrates where ‘big data’ analysis can go wrong. Our analysis of Google Flu demonstrates that the best results come from combining information and techniques from both sources,” said Ryan Kennedy, PhD, a researcher from the University of Houston. “Instead of talking about a ‘big data revolution,’ we should be discussing an ‘all data revolution,’
where new technologies and techniques allow us to do more and better analysis of all kinds.”

Under the headline “Big data: are we making a big mistake?” economist Tim Harford wrote in his Financial Times column of March 28 that, “The problem was that Google did not know—could not begin to know—what linked the search terms with the spread of flu. Google’s engineers weren’t trying to figure out what caused what. They were merely finding statistical patterns in the data. They cared about correlation rather than causation. This is common in big data analysis. Figuring out what causes what is hard (impossible, some say). Figuring out what is correlated with what is much cheaper and easier.”

Still, Hanford is optimistic that Google Flu will make a comeback and big data will find its place: “Google Flu Trends will bounce back, recalibrated with fresh data—and rightly so. There are many reasons to be excited about the broader opportunities offered to us by the ease with which we can gather and analyze vast data sets. But unless we learn the lessons of this episode, we will find ourselves repeating it.

“Statisticians have spent the past 200 years figuring out what traps lie in wait when we try to understand the world through data. The data are bigger, faster and cheaper these days—but we must not pretend that the traps have all been made safe. They have not,” he adds.

Many physicians are also skeptical. Some are already leery of big data. Dr. Starren says some physicians have recoiled at big data as insurance companies became the first in the medical world to use the approach. “They were looking at patterns of practice, and, in some cases, using that data to find ways to pay doctors less. For many doctors, big data has not been viewed as a friendly concept.”

But he maintains the technology is neutral—“not a panacea, not a doomsday machine”—but can be the doctor’s friend in trying to find an individual patient’s place in the big picture. “You’ll often hear the phrase ‘in my experience.’ What big data in health care gives us the potential to do instead is to ask, ‘Well, across everyone’s experience what happens with patients like this?’ It gives us the ability to collect everyone’s experience together.”

ECRI Institute, the Plymouth Meeting, Pa., non-profit that researches the best approaches to improving patient care, lists big data as tenth on its 2014 watch list of technologies about which C-suite hospital executives should be cautious. Rohit Inamdar, senior associate and medical physicist of the applied solutions group at ECRI, says that although there have been advances in medical records, many health facilities are lagging behind and store their data in silos that don’t communicate with each other.

He says only a handful of the largest health care systems have implemented big data approaches. As a result, these approaches have not reached their full potential. “I think of big data for health care in terms of baby steps. I see incremental movement to big data at health care facilities,” he says.

He says a government website holds up as an example a rural physician who through her implementation was able to dramatically increase cancer screening and immunizations among her patients—well above national levels. “Big data made a difference. But it was really a baby step, relative to the expectation we have of big data’s full potential.

“Overall, gathering and cleaning data to make the data usable is still in its infancy at most facilities. Health facilities may need assistance in these endeavors from organizations more experienced at collecting, aggregating, cleaning and analyzing big data. Administrators are starting to grasp the idea that big data analytics can reduce costs and improve patient care.

But it will do so only if big data analytics can provide the fifth “V”—value, which means that big data will translate to meaningful value to physicians and patients in promoting high-quality and cost-effective care.”

Howard Wolinsky is the former medical and technology reporter for the Chicago Sun-Times. He previously worked as a staff writer for American Medical News and as an instructor at Northwestern University’s Medill School of Journalism.
HICAGO PHYSICIAN

Niva Lubin-Johnson, MD, is a born leader. She has held leadership positions with organizations such as the National Medical Association and the Chicago Medical Society (CMS). Now she's helping to lead the way for physicians who, like her, are solo practitioners and general internists. She wants them to be on the forefront of quality improvement and tackle one of the toughest issues she faces when treating her patients: hypertension. “Most patients in my practice are African-American and many have hypertension and need help with management and control,” says Dr. Lubin-Johnson.

In her endeavor to help her patients, Dr. Lubin-Johnson chose to participate in an innovative initiative called “Improving Health Outcomes: Blood Pressure” (IHO: BP). Led by the Chicago-based American Medical Association (AMA) in collaboration with the Johns Hopkins Armstrong Institute for Patient Safety and Quality and the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities, in Maryland, the initiative is designed to improve care for patients by developing and disseminating a model for better detection and management of high blood pressure.

Heart disease and stroke led to more than 200,000 preventable deaths in the United States in 2010, according to the Centers for Disease Control and Prevention. Lack of access to preventive screenings and early treatment for high blood pressure was a major contributor.

The pilot work with clinical practices began last November and continues for one year. “My goal is not only to improve hypertension control for my patients,” says Dr. Lubin-Johnson, “but also to use my experience to help shape recommendations that come out of this project, such as how physicians in small practices can help patients control their hypertension. I’m hoping that my participation in this quality improvement initiative will give me access to other tools to make it easier for patients to get their blood pressure under control and keep it under control.”

The IHO: BP initiative is focusing initially on the population of patients who have hypertension and a usual source of medical care—but whose blood pressure is still too high. This group includes more than 30 million Americans. To extend the impact of its efforts, the AMA is a partner in the U.S. Department of Health and Human Services “Million Hearts” initiative, which seeks to have 10 million more Americans get their high blood pressure under control by 2017. By marshaling the physician community, the AMA's aim is to help meet and surpass this goal.

As part of the first phase of IHO: BP’s work, the AMA and Johns Hopkins are engaging five clinical sites in Illinois and five in Maryland. The sites in Illinois are Quality Primary Care (Dr. Lubin-Johnson, Chicago); Erie Family Health Center (Deborah Midgley, MD, Chicago); Northwestern Memorial Physicians Group (Mike Rakotz, MD, Evanston); Advocate Medical Group—Midwest Heart Specialists (Michael O'Toole, MD, Downers Grove); and Advocate Medical Group—Metrodocs (Stephen Sproul, MD, Mount Prospect). Collectively serving more than 60,000 patients annually, the sites comprise a diverse group of clinical practice settings—from the individual practitioner to the large health system to the Federally Qualified Health Center (FQHC).

Working together to test and build on the project's initial framework, the pilot practices will help refine this framework and develop an approach for implementing evidence-based recommendations to address uncontrolled hypertension in a busy clinical practice. The framework that the pilots have helped create is called the “M.A.P. for Achieving Optimal Hypertension Control.” Using the M.A.P. framework, clinical practice sites are testing implementation methods for evidence-based recommendations in three categories:

- Measuring blood pressure accurately, every time.
- Acting rapidly to address high blood pressure readings.
- Partnering with patients to promote self-management.
Niva Lubin-Johnson, MD, is an internist and solo practitioner participating in a pilot program to improve health outcomes by controlling hypertension. Dr. Lubin-Johnson's office is one of five clinical sites in Illinois and five in Maryland to join the initiative, led by the AMA and Johns Hopkins.
Early Benefits
Deborah Midgley, MD, is a family physician at one of those pilot clinical sites, Erie Family Health Center, an FQHC in the Chicago’s Albany Park. She says she saw immediate benefit from an early part of the pilot work—reviewing the evidence-based techniques for accurate blood pressure measurement. “While Erie has always had blood pressure control rates above the 75th percentile nationally, we saw many opportunities for improvement in our care of hypertensive patients with this project,” says Dr. Midgley. “When we looked at ‘measuring accurately,’ the first step in the M.A.P. algorithm, we realized we had patients sitting on the exam table, their feet not flat on the floor and their back not supported. We have corrected this as a result of the project.”

Common problems that account for inaccurate blood pressure measurement include:

• A full bladder: 10-15 mmHg higher  
• An unsupported back: 5-10 mmHg higher  
• Unsupported feet: 5-10 mmHg higher  
• Crossed legs: 2-8 mmHg higher  
• Cuff over clothing: 10-40 mmHg higher  
• Unsupported arm: 10 mmHg higher  
• Talking: 10-15 mmHg higher

Dr. Midgley has reconfigured the exam rooms so staff can more accurately measure blood pressure. “Our staff has been trained how to accurately measure blood pressure, but our clinic rooms weren’t set up to support correct blood pressure measurement, so this has made us much more deliberate,” says Dr. Midgley. “It’s very important for centers like ours to be able to demonstrate the quality care we’re providing to patients in need.”

Translating Evidence into Practice
The concept of translating evidence into practice is very familiar to Peter Pronovost, MD, PhD, senior vice president for patient safety and quality, and director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine. He is renowned for his work to reduce the deadly infections associated with central line catheters in the acute care setting. “We are eager to apply what we know about translating evidence into practice and culture change and to collaborate with ambulatory care teams to evolve our knowledge,” said Dr. Pronovost. “Physicians are very busy and need systems to make it easy to achieve blood pressure control. Working together, and with patients, we can help physicians achieve higher rates of control for their patients in a way that fits with the individual clinic’s context, culture and workflow.”

To help achieve that goal, Lisa Cooper, MD, MPH, has developed interventions that enhance patient-physician communication, improve blood pressure and reduce health care disparities. Dr. Cooper is professor of medicine and director of the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities, one of 10 NIH-funded Centers for Population Health and Health Disparities. One of the center’s studies, Project ReD CHIP (Reducing Disparities and Controlling Hypertension in Primary Care), an ongoing multi-level system, is informing the IHO: BP effort with valuable lessons from six community primary care practices.

Being a pilot site is not always easy. Dr. Lubin-Johnson has been surprised by the amount of work and time required to conduct practice assessments for baseline information, participate in webinars, review materials and host site visits. Still, she is determined to stick with it. “I’m focused on making this doable for my practice,” said Dr. Lubin-Johnson. “I want to be sure small practices are represented and benefit from quality improvement.”

Spurring Results
“Our colleagues in Chicago are helping the AMA galvanize a bold new professional movement in pursuit of healthier people, better health care and lower health care costs,” says AMA President Ardis Dee Hoven, MD. Noting that the AMA is in a “unique position because we reach physicians in all practice settings and specialties,” Dr. Hoven says, “we can bring them together with communities and public and private sector organizations to prevent and to achieve measurable improvements.”

The hypertension pilot is part of a new AMA strategic focus area called “Improving Health Outcomes” or IHO. The AMA is focused on cardiovascular disease (starting with hypertension) and type 2 diabetes (starting with pre-diabetes) because these conditions cause enormous suffering and death, add significant costs to the U.S. economy, and impact millions of patients and nearly all physicians. The AMA and Johns Hopkins will take what they learn from the IHO: BP pilot practices and expert advisors, including how to work with community partners to support blood pressure control, and spread effective models and methods to more practice settings and communities nationwide.

Dr. Lubin-Johnson is pleased to be part of the first phase of a national movement, and she is also focused on the value she can bring to her physician colleagues here in Chicago. “My hope is that they’ll be interested in learning about this initiative, and eager and curious to see the results,” she says. “And, they’ll see something in it for them, to help them with their patients.”

Karen Kmetik, PhD, (Karen.kmetik@ama-assn.org) is the group vice president for health outcomes at the AMA. For information about phase 2, contact AMA’s Director of Improving Health Outcomes Strategies, Donna Daniel, PhD, donna.daniel@ama-assn.org.
CHECKLISTS—LIKE THE ONES used to reduce central-line infections—can help physician practices improve outcomes for hypertension, one of America’s most common and dangerous conditions. But even for those committed to improving patient safety and health care quality, checklists alone won’t sustain positive changes without a shift in attitudes and beliefs. Fortunately, a safety model proven to succeed in the acute setting can help create and sustain change in the ambulatory setting for measuring blood pressure. Participants in a pilot program, part of the American Medical Association’s “Improving Health Outcomes” initiative, are currently involved in applying this model to their practice settings. Four Chicago-area physician practices and one community health center are among the sites piloting this safety-to-quality approach.

Just as the checklist safety principles are intended to avoid patient harm, ensuring quality care in screening for and treating patients with high blood pressure can prevent the development of heart disease and stroke down the road. The principles of safe design are to:

1. Standardize
2. Create independent checks
3. Learn when things go wrong

Applied to hypertension control, standardization ensures blood pressure is measured correctly. If it’s not, independent checks will catch errors. Changing the process if mistakes occur closes the loop of safe design.

The Comprehensive Unit-Based Safety Program (CUSP) helps practices put the principles of safe design into action. CUSP is a five-step process designed to change a practice’s workplace culture to bring about significant improvements in quality and safety. Developed by the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality, a partner in the AMA’s work to improve health outcomes around hypertension, the framework aims to empower staff to drive quality improvement efforts in their clinical areas.

The five steps of the CUSP model are:

1. Train staff in the science of safety. Understanding how system factors affect care delivery is key to making lasting improvements. The program provides a 20-minute video developed by Armstrong Institute Director Peter Pronovost, MD, which describes how system factors can negatively impact care and lead to preventable harm.
2. Engage staff to identify defects. In this second step, staff members identify patient safety defects in their work areas and explain how these defects may contribute to a patient’s uncontrolled hypertension. For example, the position of a wall-mounted sphygmomanometer could prohibit clinical staff from properly positioning patients to ensure accurate blood pressure measurements.
3. Partner with a senior executive or someone who has decision-making power over the practice. This step helps the practice teams bridge the gap between frontline staff and executive leadership. The active involvement of practice leaders in improvement efforts helps develop a shared understanding of issues, establishes support for implementing and evaluating the plan, and gives teams the leverage they need to create real change in their practice.
4. Learn from defects. In this phase, staff members improve care by examining a defect to understand what went wrong, why it happened, what was done to reduce risk and how to prevent future risks.
5. Implement tools to improve. The practice team then uses tools to address areas that need improvement. In the case of the “Improving Health Outcomes: Blood Pressure” initiative, the AMA and collaborators at Johns Hopkins are partnering with 10 pilot practices in two states to develop and test a set of evidence-based recommendations and associated tools called the “M.A.P. for achieving optimal hypertension control.”

Using CUSP enables cultural change within a practice, providing a means to shift staff attitudes, values and beliefs. Because all staff must use their expertise to implement CUSP, the entire team is empowered to continue the process as a new norm. In the AMA pilot program, the practice sites also will benefit from lessons learned from Project RedCHIP (Reducing Disparities and Controlling Hypertension in Primary Care) in their integration of quality improvement and patient-centered care principles. Lisa Cooper, MD, director of the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities, and her team are leveraging their expertise in hypertension control improvement.
Approaching End-of-Life Conversations

As hard as it may be for the physician and the patient, clear and compassionate discussion about choices will serve everyone. By Randi Belisomo

What’s the Most Difficult Thing You Have Ever Had to Tell a Patient? Was it so hard that it simply went unsaid?

In medicine, language matters. When a patient is diagnosed with a terminal disease, clarity in communication and word choice can have immeasurable impact on how patients choose to spend their remaining time. Once communicated, the hard-to-say and even harder-to-hear truth can shift the entire focus, or lack thereof, in an examination room. Instead of fielding inquiries about scan results or a research trial, physicians may guide patients and their families to look at a bigger picture, without being caught up in the clinical details.

- Is it time to take the last trip to Florida? Yes.
- Is it time to stop working in order to be together as a family? Yes.
- Is it time to communicate everything that patients have been meaning to share with the kids? Yes.
- What are your patients waiting for? You.

Acknowledging Reality

Resolution, reconciliation, and the peace, grace and comfort most of us hope for at our time of death can only come by first acknowledging the reality that death is taking place. That someone is indeed dying. A recent study reported in the New England Journal of Medicine evaluated patients’ understanding of the goal of their cancer treatment. More than 70% of patients enrolled did not understand that they had incurable disease.

Another study published in the Journal of Clinical Oncology demonstrated that better end-of-life dialogue between doctors and patients results in different care options: those who talk with their doctors about end-of-life care at least one month before they die are more likely to choose therapy that is less aggressive and aimed more at making them feel better. Authors suggested that having such discussions soon after a terminal diagnosis gives patients the time to process the idea that their life is nearing an end. Therefore, they are empowered to make thoughtful, informed decisions about their treatment.

One of the biggest barriers to facilitating quality end-of-life discussions—the kind that lead to patient empowerment in the form of advance directives, finalizing legal and estate plans, creating a family legacy and meaningful use of one’s time—is not always the patient; often, it is the doctor. Even the most experienced and skilled physicians sometimes pause, or avoid the inevitable altogether. Noted physician and author Abraham Verghese wrote, “I had always felt inexpert when a patient was near death. Give me a patient with massive gastric bleeding or ventricular fibrillation and I am a model of efficiency and purpose. Put me at a deathbed, a slow dying, and purpose is what I lack.”

Imagining Yourself as the Patient

But a physician’s purpose near death is paramount. Physicians are often uncomfortable delving into a problem they are unable to fix. While doctors may not be able to fix a problem, they have so much positive power in their ability to relieve suffering and provide comfort—actions that could mean everything to dying patients and their families in the most stressful time of their lives. How to do this?

Empathy

Physicians must put themselves in their patients’ place and allow the time to do it. It may be the third such conversation a doctor has facilitated that day, but it is the first time the patient has ever heard it. It is scary, overwhelming, sad and uncomfortable. But however hard it is for a physician to say, it is most likely the hardest thing a patient has ever had to hear.

Honesty

Don’t sugarcoat reality. Doctors must tell patients the facts of their condition, because only in knowing can they make a fully informed decision about how best to proceed with whatever time is left.

Clarity

Euphemisms may be easier to use, but what physicians often say is not what patients may hear. Clear and compassionate language matters.

Planning

One of the hardest things for patients and families upon hearing such dire news is that they often interpret it to mean there are no more options available; that there is nothing physicians can do. “No further treatment is available” is the worst thing a patient can hear, and it is not true. Patients and families need something to do, and physicians can provide that in providing a care plan. There is comfort care.

Easing of Pain

Enabling a patient to have the best day possible—that is a true goal of care. But even the greatest medical communicators face plenty of barriers, some obvious and often discussed; patient denial is a common one, as is hope in some “miracle.” But others are more subtle.

Fear of Disappointing

It may seem strange that often in end-of-life cases, patients are
afraid to bring up the reality of death because they fear letting down their health care team. Somehow, it would be seen as a failure on their part if they are declining rapidly. In the course of interviewing so many at the end of life, this fear is a reality that comes up time and time again. Physicians are trained to make patients better, and if a patient isn’t getting better, it is disappointing. That patient doesn’t want to bring up what may be perceived as a medical failure. Don’t make the patient address it first—that’s the job of the physician.

This fear of disappointment must be eliminated to enable quality end-of-life care. How can a physician shift from treating symptoms to overall well-being from disease therapy if he or she isn’t receiving the full story from a patient? This fear of disappointment can be lessened by clear language.

- Are you afraid of dying?
- Are you afraid of pain?
- Are you afraid of being alone?

These questions are more likely to lead to comprehensive and attentive care than the common request: “Tell me about your symptoms.”

FEAR OF ABANDONMENT
That shift to caring for overall well-being instead of treating disease is one that providers must let patients know they do, too. For example, if hospice is the next step, let patients know that not only will they get outstanding comfort, but also if they need to call, they can. At the end of life, everything is seen as a loss. Is this the last time I’m going to see this person? Is this the last time I’m going to venture outdoors? Is this the last time I may enjoy a meal? Don’t allow a patient encounter to feel like it is one more thing that needs to be mourned, one more loss, or one more uncomfortable situation for the patient.

FEAR OF ISOLATION
If patients are nearing the end of life but are well enough to be coming back and forth to the doctor’s office, they may feel like a sore thumb. To be the sickest person in the waiting room is terribly lonely. This fear correlates with the fear of disappointing the care team; patients need to know that their physician has cared for patients in their situation, will care for more in the future, and will continue to care for him or her. It is so comforting for a patient to know they are not the only one.

It’s Up to You, the Physician, to Provide This Gift of Compassion
It is practically impossible to provide quality end-of-life care without acknowledging the reason for it. The clear and compassionate truth empowers patients to gain what they want the most in times of tremendous loss. This gift is one only the physician can give, and do so graciously.

Randi Belisomo is the president and co-founder of Life Matters Media, a non-profit that provides information, resources, and support for those involved in end-of-life decision-making. She is a current student of bioethics and health care policy at Loyola University Chicago. She serves on the board of the Chicago End of Life Care Coalition and is a member of the Association of Health Care Journalists. For information, go to www.lifemattersmedia.org.
Advocacy in Action
Chicago physicians spur new patient care reforms at ISMS House of Delegates

FROM PUBLIC health to legislative advocacy, the Chicago Medical Society (CMS) is the collective voice for Cook County’s 17,000 physicians, speaking up on issues of common concern. As part of that process, CMS is a wellspring of resolutions that go on to shape new laws statewide and nationally. That tradition continued April 25-27 at the Illinois State Medical Society’s Annual House of Delegates, where the Chicago delegation pushed for new patient and physician protections. Those initiatives now move on to the General Assembly and ultimately, the halls of Congress. Here is a recap:

Medical Information and Its Uses (By Thomas J. Chorba, MD)
This measure addresses the U.S. government’s efforts to gather physician and patient encounter data, including demographic and financial data. Accuracy and accessibility are key concerns for CMS. The initiative directs ISMS and AMA to work with agencies involved in the collection, receipt, and transfer of data. The language says the public should be informed of the aggregate information being gathered, and to which entities this information is being distributed or sold.

Streamlining Insurance Plan Drug Formularies (By David J. Palmer, MD, and Philip B. Dray, MD)
The current authorization process for drug formulary alternatives endangers patients, while creating major hassles for medical practices. A new CMS policy sets up a communications procedure to avoid such administrative obstacles. The policy says that when a pharmacy reports back to a prescriber that a drug is not on the formulary, or needs pre-authorization, the pharmacy will consult the insurer for formulary alternatives, notify the prescriber of these alternatives, and obtain the prescriber’s authorization for the substitution within 72 hours. In addition, CMS urged the AMA to advocate through the appropriate channels to improve communication around drug formulary issues, and for lawmakers to implement a uniform authorization form.

Both CMS and ISMS pledged support for HB 3638, a bill that requires insurers to decide within 72 hours whether they approve the cost of a patient’s prescription. The bills says that insurers must give detailed information if the prescription is denied, including substitute bio-equivalent medications, and outline an appeals process.

Safer Chemicals Policies (By Peter Orris, MD, MPH)
Public exposure to toxic chemicals is a growing threat in the United States. And CMS recently adopted policy that supports modernizing the 1976 Toxic Substances Control Act. Now that the National Academies of Sciences has recommended modernizing U.S. chemical health evaluations,
CMS is urging ISMS and AMA to review the NAS recommendations, which call for chemical testing and risk assessment, and setting human exposure limits. As the CMS resolution points out, testing that is not done correctly, or is out of date, may result in unsafe but legally permissible levels of chemical exposure. Among TSCA’s failings: chemical producers are not required to disclose hazard information on the 80,000-plus chemicals used in commerce, or on the 2,000 new chemicals introduced each year; the government must meet an excessively high standard of proof before taking action, primarily after chemicals have caused harm; the Act does not encourage prevention through safer alternatives.

Nutritional Guidelines for Food Banks and Pantries (By Susan B. Kern, MD)
This CMS measure aims to mitigate the health and social consequences of obesity. Donations to food banks and pantries do not have to meet nutritional guidelines. The lack of refrigeration and high cost of fresh fruits and vegetables make stocking healthy food a challenge for these facilities. In addition to creating new policy, the initiative directs ISMS and AMA to work with state and federal agencies, as well as food banks and pantries, to utilize existing national nutritional guidelines. The measure calls for strategies to dispense fresh fruits and vegetables that meet with state and federal food safety regulations.

e-Cigarette Smoking Ban (By Howard Axe, MD, and Sachin “Sunny” Jha, MD)
Electronic Nicotine Delivery Systems (ENDS), or e-cigarettes, represent the latest front in the war on smoking. The City of Chicago, which recently banned the use of e-cigarettes in public indoor buildings, is ahead of the state when it comes to outlawing e-cigarettes. Per the CMS resolution, ISMS will push for a statewide ban on these devices in public indoor settings, adding the provision to the existing state smoking ban. The resolution seeks AMA action.

Here are highlights:

- Label and regulate e-cigarettes as tobacco products and drug delivery devices.
- Address the minimum purchasing age, locations of permissible use, advertising, promotion, and sponsorship.
- Require transparency and disclosure concerning the design, content and emissions.
- Require strong labeling that warns of potential consequences, restrict marketing as tobacco cessation tools, and restrict the use of characterizing flavors.
- Support basic clinical and epidemiological research.
- Require secure, child-proof, tamper-proof packaging and design.

Handicapped Parking Placard Program (By Howard Axe, MD)
The state’s stringent new parking placard rules penalize physicians for unintentional errors in reporting. Both CMS and ISMS strongly object to monetary penalties and discipline for errors in completing reporting forms, unless there is a clear effort to falsify or mislead state officials. In addition to new policy that expresses strong objection to penalties, the CMS measure led to new ISMS policy that patients seeking handicapped placards need appropriate medical evaluation. The policy recognizes physicians as an integral part of the Secretary of State’s efforts to prevent fraud, ensuring that parking placards are given only to those who genuinely need them.

Protect Physician Certification (By Makis Limperis, MD)
This CMS resolution urged the AMA to fight back against insurers and hospitals requiring physicians to retake costly certification exams. Moreover, the exams are money-making schemes that enrich the specialty boards, according to the sponsor.

The Affordable Care Act ties quality reporting and Medicare payment to Maintenance of Certification (MOC), a process developed by physician specialty boards to evaluate skills and abilities. Maintenance of Licensure (MOL) requires physicians to provide evidence they are participating in continuous professional development as a condition of licensure. At this time, the IDFPR is not taking immediate steps to implement MOL in Illinois.

Some physicians argue that the exams do not reflect actual conditions in medical practice. But those involved in education and accreditation counter that recertification provides assurance to the public that physicians are keeping up with new medical knowledge. The real issue is the misuse of exams by testing companies, hospitals and insurers.

ISMS will monitor the AMA’s efforts to evaluate both MOC and MOL, and provide input to ensure the validity of these processes. MOC and MOL must be efficient, effective, evidence-based, and sensitive to the use of physicians’ valuable time and resources. ISMS also will monitor the AMA’s Principles on Maintenance of Certification.

CMS and ISMS oppose board-certification as the sole criterion for denying credentials.

ABMS Compromising Lifetime Certifications Retroactively (By Jerrold B. Leikin, MD)
If the guiding principle behind MOC is part of licensure-based continuing medical education, then MOC is redundant, this resolution said. Nor has MOC demonstrated improvement in patient care metrics and outcomes, the sponsor argued. Retroactive limitations on lifetime board-certification violate the original guidelines set forth by the American Board of Medical Specialties. ISMS will urge AMA to approve policy that no qualifiers or restrictions should be placed on lifetime ABMS-recognized certifications.

“At this crossroads in the nation’s history, CMS provides a collective voice for Cook County’s physicians.”
A Cardinal Sin
ISMS guards against legislative micromanagement of medicine
By William A. McDade, MD, PhD

MICromanagement is regarded as one of the cardinal sins of leadership, and for good reason. The micromanager inevitably wastes time making decisions about issues with which he or she has little experience. The whole team suffers as a result. When legislators try to micromanage, the consequences can be devastating—especially when it comes to medicine.

Of course, I’m not saying the legislature should wash its hands of anything related to health care. The Illinois General Assembly has a strong interest in addressing significant public health threats, and it has the authority to regulate health professionals who care for the people of Illinois. Every day, the Illinois State Medical Society (ISMS) works cooperatively with legislators to develop sound policy that protects patients and allows physicians to exercise their medical judgment.

Unfortunately, legislators sometimes try to use their regulatory authority in ways that would ultimately do more harm than good. Three public health issues stand out as recent examples of how legislators sometimes try too hard to make a difference, and end up legislating the practice of medicine instead:

• Child abuse is a major problem nationwide, and health care professionals are on the front lines of detecting and reporting abuse. SB 3421 would have required that anyone licensed by IDFPR who is also a mandated reporter, including every physician, must receive regular training on recognizing child abuse. This may seem reasonable at first, but a large portion of physicians never encounter children in their practices, and many do not see patients at all.
• Opioid addiction, which includes addiction to prescription medications as well as our state’s heroin epidemic, is another example of this phenomenon. The Illinois House of Representatives Heroin Crisis Task Force is currently considering a wide range of options, including mandatory CME, mandatory use of the Prescription Monitoring Program prior to prescribing, separate licensure of so-called “pill mills,” codification of particular evidence-based guidelines, toxicology screening of patients who are prescribed opioids, and much more. Final legislation has not yet been introduced, but many of these mandates would place undue burdens on physicians and patients.
• Hepatitis C is a significant public health threat that affects over three million Americans, and in 2013 the State of Illinois set up a Hepatitis C Task Force to research the issue and recommend action. This task force has asked why physicians do not always follow CDC guidelines for Hepatitis C screening, which recommend that all adults born 1945-1965 receive testing for Hepatitis C. SB 2670 would have mandated this screening in Illinois.

The CDC guidelines are meant to assist in the clinical practice of medicine, not to overrule a physician’s medical judgment. While increasing screening and reducing deaths from Hepatitis C are important goals, mandated screening is the wrong approach. Many insurance carriers do not fully cover the cost of screening or treatment. There undoubtedly would be many screened individuals who do not have Hepatitis C, and the resources expended on such a mandated screening effort would have a significant adverse impact on the use of health care dollars.

Similar stories can be told about testing of newborns for the CMV virus, identifying elder abuse, and a host of other issues. The temptation is strong for well-meaning legislators to turn clinical guidelines into state law, mandate particular topics for CME, and otherwise micromanage medicine. Fortunately, ISMS is here to help make sure good intentions do not give way to bad policy.

Physicians take seriously our responsibility to keep our skills sharp and to treat each patient according to our medical judgment. There are only so many hours in a day, and the more time a physician must spend on mandated screenings and required CME topics that aren’t relevant to his or her patients, the less time he or she has for what really counts.

ISMS works hard every day to make sure our senators and representatives understand this. We work with them individually to craft responsible legislation, and we testify before legislative committees and task forces on behalf of Illinois’ physician community. We also bend over backwards to provide an abundance of rich and relevant CME materials. It’s no coincidence that we offer access to resources on recognizing and reporting child abuse, responsible prescribing of opioid pain medications, and countless other topics.

Physicians have the training and experience to know what topics are relevant to their practices. We have the professional responsibility to stay current on those topics and on the appropriate guidelines to help us treat our patients. And thanks in part to ISMS, we have ample opportunity to do so. All we need now is for the state legislature to let us do what we’re trained to do.

Dr. McDade is the 171th president of the Illinois State Medical Society.
S.M.I.L.E.
(Saving More Illinois Lives through Education)

A project of the Chicago Medical Society and the Illinois State Medical Society, supported by the American Heart Association

HANDS-ONLY CPR GIVEN PROPERLY AND IMMEDIATELY TO VICTIMS OF SUDDEN CARDIAC ARREST CAN SAVE LIVES
- Less than 8% of people who suffer cardiac arrest outside of a hospital survive.
- Less than 33% of out-of-hospital sudden cardiac arrest victims receive bystander CPR.
- Effective bystander CPR, provided immediately after sudden cardiac arrest, can double or triple a victim’s chances of survival.
- The mission of SMILE is to disseminate information to the general public about the importance of learning basic emergency resuscitation skills such as “hands-only” CPR.

TWO SIMPLE STEPS—HANDS-ONLY CPR:
1. CALL 911
2. START CHEST COMPRESSIONS, PUSH HARD AND PUSH FAST (at least 100 times/min)

If you are interested in organizing a SMILE presentation in your community or interested in becoming a SMILE volunteer, contact Meredith Oney at the Chicago Medical Society 312-670-2550, ext. 326, or email oney@cmsdocs.org.
Calendar of Events

**JUNE**

**7-11 AMA Annual House of Delegates Meeting** The legislative and policymaking body of the AMA transacts all business not otherwise specifically provided for in its Constitution and Bylaws, electing general officers except as otherwise provided in the Bylaws. CMS actively participates in the AMA’s policymaking meetings, advocating for both 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. The meeting takes place in Chicago at the Hyatt Regency Hotel. For information, please go to www.ama-assn.org.

**12-13 Physician Legal Issues Conference (2014)** This two-day event is intended for all physicians and health care attorneys who will give a medical-legal update of changes and trends in the health care delivery system, their impact on the practice of medicine, and various strategies to meet these challenges. Core topics will cover: health care reform and payment; physician integration and collaboration on medical staff; hospitalists and continuity of care—an ethical dilemma; buying, selling and merging physician practices; fraud & abuse; surviving fraud audits and working with defense counsel; HIPAA/FHIPAA/ HITECH and HIPAA enforcement; telemedicine; medical staff issues; physician employment agreements; Stark law/anti-kickback fundamentals; physician wellness and disruptive behavior; medical professional liability; and a diversity presentation and reception. The Chicago Medical Society is co-hosting the event with the American Bar Association’s Health Law Section. 8:00 a.m.-8:00 p.m. (Thursday) and 8 a.m.-4:30 p.m. (Friday); Palmer House Hilton, 17 E. Monroe St., Chicago; 10 CME credits. Register online at: www.cmsdocs.org or please contact Elvia at emedrano@cmsdocs.org or 312-670-2550, ext. 338.

**14 Advanced Cardiovascular Life Support (ACLS) Recertification Course** Intended for all physicians, residents, and allied medical professionals. ACLS is a protocol for managing victims suffering from severe cardiac conditions and other medical challenges. Through ACLS training participants may develop the expertise and skills needed to use this life-saving process properly and safely. To qualify for ACLS training you must be a medical professional such as a registered nurse or physician. Unlike BLS (Basic Life Support), which doesn’t require comprehensive education and training, ACLS certification is required for health care providers working in acute care settings and by providers of emergency services. The majority of hospitals and emergency services require accreditation by the American Heart Association (AHA). Speaker(s): Vemuri S. Murthy, MD, Program Coordinator and Teaching Faculty, Resurrection Healthcare Training Center, Chicago, and Dennis McAuley, EMT-P, Course Director, Training Center Coordinator, Resurrection Healthcare Training Center, Chicago. 8:30 a.m.-4:00 p.m.; Chicago Medical Society, 33 W. Grand Ave., Third Floor, Chicago; 7.0 CME credits; CMS member/staff: $185; non-member/staff: $235; residents: $145. Register online at: www.cmsdocs.org or please contact Elvia at emedrano@cmsdocs.org or call 312-670-2550, ext. 338.

**JULY**

**10 Public Health Committee General Meeting** This meeting is intended for subcommittee members, but is open to interested CMS members as well. 4:00 p.m.-5:00 p.m.; Conference Call. To RSVP, please contact Meredith at 312-670-2550, ext. 326, or oney@cmsdocs.org.

**16 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.; online. Questions, please contact Ruby 312-670-2550, ext. 344; or rbahena@cmsdocs.org.

**17-20 Headache Update 2014** This event is presented and jointly sponsored by the Diamond Headache Clinic Research & Educational Foundation, the Diamond Inpatient Headache Unit at Presence Saint Joseph Hospital, and the Primary Care Network. Course Director: Merle L. Diamond, MD; Disney’s Grand Floridian Resort & Spa, Walt Disney World Resort, 4401 Floridian Way, Lake Buena Vista, Florida 32830. Approved for 24 AMA PRA Category 1 Credits. For information, please visit www.dhecfdn.org.

**AUGUST**

**13 OSHA Training—Webinar** Intended for physicians, physician assistants, nurses, practice managers, and dental professionals who risk potential exposure to bloodborne pathogens. Participants will learn to: implement a training program for health care employees who may be exposed to bloodborne pathogens; identify appropriate personal protective equipment (PPE); develop an emergency response plan; create a written exposure control plan for health care workers assigned as first-aid providers; and develop a strategy to prevent the spread of pandemic flu within the practice. Speaker: Sukhvir Kaur, Compliance Assistance Specialist; 2:00-4:00 p.m.; St. Francis Hospital, 355 N. Ridge Ave., Evanston, IL; 2 credits; $99 per CMS member/staff; $139 per non-member/staff. Register online at: www.cmsdocs.org or please contact Elvia at emedrano@cmsdocs.org or 312-670-2550, ext. 338.
Personnel Wanted

America's Disabled, a Chicago-based not-for-profit is looking to hire IM/FP physicians to make house calls to the elderly home-bound. We offer competitive compensation, malpractice coverage and an EMR. Please email CV to dberliant@totalhealthcaregrp.com or call 773-774-7300. 5906 N. Milwaukee Ave., Chicago, IL 60646. www.physicianhomevisits.com.

Welcome New Members!
The Chicago Medical Society welcomes its newest members. We are now six voices stronger!

Student District
Edith Graham
Julia M. Graham
Aaron M. Silver

Resident District
Lauren Marie Guggina, MD
Wayne K. Lee, MD
Caroline J. Novak, MD

Medical office/urgent care building for lease; 1650 Maple Ave, Lisle, IL 60515; 1,500-4,000 sq. ft. available, $19.50 per sq. ft. Single story, 20-30 car parking lot. Email: vgi028@aol.com or vino@aol.com. Fax: 847-398-4585 with serious inquiries.

Medical director (part-time). America's Disabled specializes in house calls to the elderly homebound. Looking for assistance in developing clinical priorities and procedures. Must be comfortable with EMRs. Board-certified in IM/FP. Flexible hours. Practice located at 5906 N. Milwaukee Ave., in Chicago. Contact Daniel Berliant at 773-774-7300 or send CV to dberliant@totalhealthcaregrp.com. www.physicianhomevisits.com

Outpatient surgical facilities, family planning centers, and family practices seeking physicians of all specialties, including anesthesiology, urology, obstetrics-gynecology, internal medicine, and gastroenterology. Needed in the Chicago area, northwest and western suburbs on a part-time basis. Please fax CVs to 847-398-4585 or email to administration@officegci.com.

Office/Building for Sale/Rent/Lease


Family medicine practice for sale. Profitable practice in Winnebago County; 2,200 active files; $430,000 SDE in 2013. EHR in place. Favorable lease. Contact Terry Flanagan terry@practicebrokers.com or 877-988-0911.

Gynecology practice for sale. Profitable newly established practice in Kane County, plus satellite office. EHR in place; newer equipment; $264,000 SDE in 2013 with 1,700 files. Contact Terry Flanagan terry@practicebrokers.com or 877-988-0911.

Business Services


Physicians’ Attorney—experienced and affordable physicians’ legal services including practice purchases; sales and formations; partnership and associate contracts; collections; licensing problems; credentialing; estate planning; and real estate. Initial consultation without charge. Representing practitioners since 1980. Steven H. Jesser 847-424-0200; 800-424-0060; or 847-212-5620 (mobile); 2700 Patriot Blvd., Suite 250, Glenview, IL 60026-8021; shj@sjesser.com; www.sjesser.com.
For Clinical ethics and palliative care specialist Julie Goldstein, MD, the issue of medical ethics arose quickly on her career path. “The first hour of my first job as an attending, a patient was in the ICU with congestive heart failure,” she says. “He was struggling to breathe but he didn’t want to be intubated. The resident reported that after his last extubation, the patient was adamant that he did not ever want to be reintubated. But the patient’s primary care physician told the resident over the phone that he was probably not decisional due to hypoxia, and instructed him to intubate the patient. I had no idea how to address the issue.”

She subsequently completed a fellowship at the University of Chicago’s MacLean Center for Clinical Medical Ethics. After her fellowship ended in 1996, she took a position at Advocate Illinois Masonic Medical Center, eventually becoming chief of the section of medical ethics, where she still works today. After a few years at Illinois Masonic, she was certified in hospice and palliative medicine, and she and advanced practice nurse Lori Hedges started the Palliative Care Consultation Service. “Over time, I became most interested in advance care planning. More and more, there is recognition of the importance of advance care planning in matching treatment plans with patient wishes and with what is medically possible.”

“With advance care planning, the idea is to plan for different possibilities well before a patient is at an acute stage of deterioration,” she continues. “It is based on the rationale that we have the right to decide what happens to our bodies, which of course is a core value in this country.” The other critical aspect of advance care planning is for patients to identify a trusted person who could serve as a substitute decision-maker if they lose the ability to speak for themselves.

Dr. Goldstein acknowledges that these conversations can be time consuming, especially with seriously ill people. “A more detailed conversation that addresses specific wishes for treatment at the end of life is required for people who are actually near the end of their lives. A screening question those of us in palliative care always ask is, ‘Would I be surprised if the patient died within the next year?’” she says. If the answer is “no,” that is a patient with whom an advance care planning discussion focusing on end-of-life wishes is appropriate. “Patients with chronic, progressive conditions often live their daily lives not understanding what is to come, even though we as physicians do. If physicians and patients can have a collaborative discussion, where the physician elicits patient values and wishes, while clearly outlining the patient’s prognosis and possible complications, then the patient will be more comfortable with his or her medical care. This type of planning also results in less distress for loved ones.”

On a personal level, Dr. Goldstein has two daughters in college. “I am a breast cancer survivor, so balance and self-care are critical to me; I try to stay rested, work out, eat well, and socialize outside of work.” She participates in a regular meditation group and takes classes in long-form improvisation. “These activities are grounding for me,” she says, “and they are also very helpful to the work I do.”

WHO’S WHO

Providing Ethical Care
A passion for helping patients with end-of-life decisions

By Cheryl England

Dr. Julie Goldstein has dedicated her career to helping physicians and patients work together to plan for end-of-life care before a crisis occurs.

Dr. Goldstein’s Career Highlights

In addition to her demanding positions as medical director and chief of clinical ethics, Dr. Goldstein also serves as clinical lead for the Advocate systemwide program for educating clinicians on how to conduct advance care planning conversations with people with chronic illness who are starting to experience functional decline. She was the co-convener and is the executive lead for the POLST Illinois Taskforce (polstil.org) and she is the only certified state faculty member in Illinois for the Respecting Choices Last Steps POLST Advance Care Planning Education Program. She is an executive committee member and founding past-president of the Chicago End-of-Life Care Coalition (cecc.org) and she has worked with multiple organizations over the past decade to improve upon statutorily advance directives.
“As physicians, we have so many unknowns coming our way...

One thing I am certain about is my malpractice protection.”

Medicine is feeling the effects of regulatory and legislative changes, increasing risk, and profitability demands—all contributing to an atmosphere of uncertainty and lack of control.

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