

# MINNESOTA MEDICINE

JUNE 2015

STOLEN  
NUMBERS  
000  
VIOLATED  
TRUST

IDENTITY THIEVES  
ARE TARGETING  
PHYSICIANS  
BUT YOU CAN TAKE STEPS  
TO PROTECT YOURSELF  
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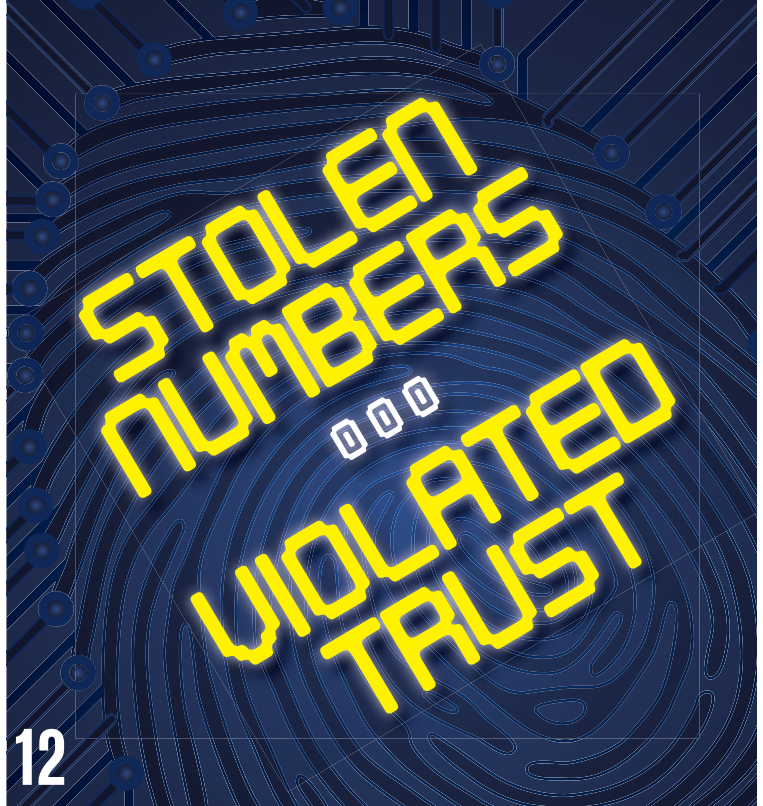
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PHOTO BY SCOTT WALKER

Charles R. Meyer, M.D., Editor in Chief

We live in an Orwellian time with multiple Big Brothers spying on us through electronic portals.

## Who's watching us?

Recently, I wanted to make a change to one of my credit cards. After navigating the phone tree, I spoke with a man who wanted to verify that I was who I said I was. He requested the usual demographic information including the last four digits of my Social Security number. He then gave me a little multiple choice quiz. "In the past 18 months, have you purchased one of these cars?" Yes I had, how did you know? "In the past 12 months have you ...?" and he listed four different financial transactions including refinancing a mortgage. This was spot on, too. At least one of the three remaining questions also suggested that this guy was able to peek into my life in a way that I would never have suspected. Although most of these questions were about financial transactions that were publicly accessible, the call did raise uncomfortable questions in my mind: "How much do 'they' know about me?" and "Who are 'they'?"

These are questions with daily echoes in the news. Target announces a major breach in its credit card operations resulting in fraudulent use. Following Edward Snowden's revelations, the NSA is found to be monitoring phone traffic from a wide swath of the American public. Social media sites such as Facebook, Twitter and Snapchat deal with thousands of unwanted incursions. Whether "they" are the institutions that legally mine our data or the individuals who make illegal incursions into our personal and financial lives, "they" seem to be raiding our privacy almost daily.

And health care is no exception. The insurance giant Anthem announced that demographic information including the Social Security numbers of more than

70 million people had been pirated. A few years ago, a laptop containing patient information that belonged to a Fairview contractor was stolen. Pilfered DEA numbers feed counterfeit prescriptions. Despite the seemingly stringent safeguards of HIPAA and the Minnesota privacy act, the security of patient and physician information is in jeopardy.

We live in an Orwellian time with multiple Big Brothers spying on us through electronic portals. It's enough to generate more than a dose of paranoia, except that we also live at a time when every day millions reveal intimate details about themselves to the world through social media. Facebook is not a secure phone line, and personal information shared on it can result in embarrassment or even job dismissal. So even if we plugged all the leaks in our systems, we likely would continue to trust strangers with the intimate details of our lives.

There is no question that the dizzying pace of technology has made the problem of privacy ever more tangled, and the future promises additional snarls. As genomic medicine enters the exam room, dicey questions arise about what information should be revealed to whom. With the advent of the "Internet of things," it won't just be our computers or phones that fall prey to hackers but also the sensors that read our blood pressure and heart rate.

This brave new world calls for us to ask and answer two fundamental questions: How much do we want "them" to know about us? And who are the "them" that we will trust with that knowledge? Stay alert.

Charles Meyer can be reached at meyer073@gmail.com.



# Winging it

David H. Ahrenholz knew he wanted to be a butterfly expert long before he knew he wanted to be a surgeon. It all began in third grade, when he wanted to help his older sister collect insects for a science project. He recalls how his mother fashioned a net out of petticoat material so stiff it “stood up like a dunce cap.”

His interest in the beautiful insects soon became his passion. When he wasn't in the fields on the outskirts of Waterloo, Iowa, where he grew up, he was in the public library checking out as many books about butterflies as he could. When he had read all they had in their inventory, he moved on to the collection at Iowa State Teacher's College (now the University of Northern Iowa) in nearby Cedar Falls.

In high school, Ahrenholz purchased a single-lens reflex camera. “People didn't seem too interested in looking at my specimens, so photography seemed a good way to share all that I was learning about them,” he says. He soon began selling his photos.

By the time Ahrenholz enrolled in Luther College in Decorah, Iowa, his goal was to become a biology professor and solve the mystery of metamorphosis. But when he took a job as a hospital orderly, he saw medicine as a better career path. After completing his surgical residency in 1982, Ahrenholz joined Regions Hospital in St. Paul, where he began working as a trauma and burn surgeon. Today, he co-directs the



PHOTO BY MIKE KRIVIT

Surgeon David Ahrenholz is an internationally known lepidopterist.

Burn Center and is an associate professor of surgery at the University of Minnesota.

Since the 1980s, Ahrenholz has been traveling to South America (these days, he goes twice a year for several weeks at a stretch) to collect specimens and photograph butterflies. He also has explored

species in the Rio Grande Valley and parts of Florida.

In 1986, Ahrenholz had his first meeting with taxonomists at the Smithsonian, who asked if he would collect specimens for them during his travels. The Smithsonian lent him specimen storage cases, which now hold close to 14,000 specimens

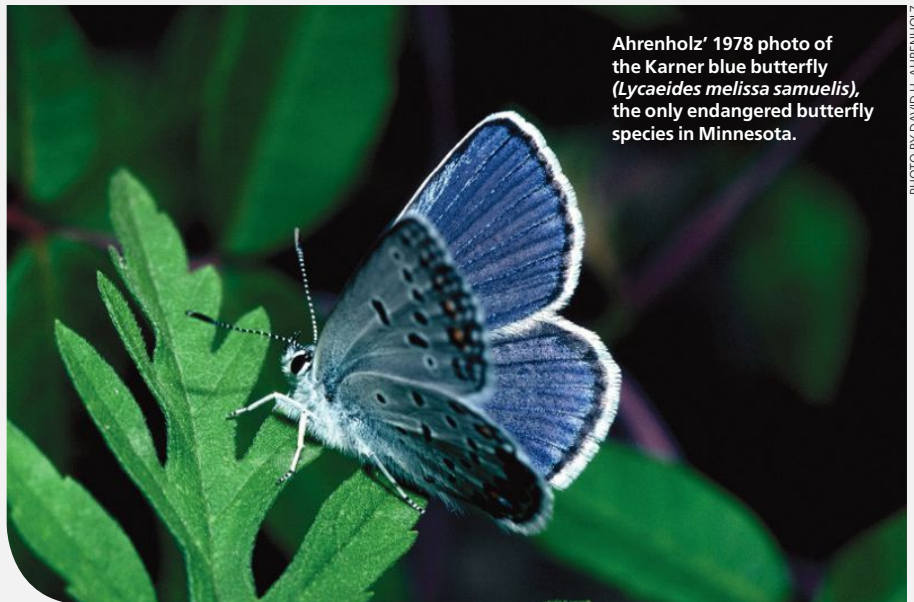
## Winging it

(continued from previous page)

he has collected. Ahrenholz will one day bequeath the butterflies to the Smithsonian for their permanent collection.

Ahrenholz has had his photographs published by the Audubon Society and in *National Parks* magazine, as well as in multiple books. He even sold one to National Geographic, which used it in a film-strip. (Not wishing to upstage other nature photographers, he no longer sells his photographs.) Three species have been named after him, and he has had the opportunity to name a few himself—after his wife, his younger sister and a retired Marine Corps colonel who often accompanied him on his travels.

Because his fieldwork takes him to high elevations, Ahrenholz climbs about 60 flights of stairs a day before a trip to stay in



Ahrenholz' 1978 photo of the Karner blue butterfly (*Lycaeides melissa samuelis*), the only endangered butterfly species in Minnesota.

PHOTO BY DAVID H. AHRENHOLZ

shape. “You have to be willing to climb the equivalent of the IDS Tower every morning because the best way to find butterflies is to climb a steep hill above the tree canopy and look down,” he explains.

Ahrenholz says he likes the fact that as a lepidopterist, he is always discovering.

“You spend the day in the tropical rainforest, and then you come back to your room, take a cold shower, put your feet up and say, ‘You know, today I saw something that I never knew existed on the face of the earth,’” he says. “And it happens day after day.”

## With the touch of a finger



Mayo Clinic and HealthPartners are among a growing number of health care organizations using biometrics to allow patients to access their health information on mobile devices.

Both recently began using Touch ID, a fingerprint recognition feature that works with select Apple devices. By touching a button on the screen, the system securely stores, scans and verifies the print, allowing the user to log in without having to enter a username or password.

Patients can use Touch ID to access the myHP mobile and Mayo Clinic apps. myHP allows users to schedule appointments, view test results and immunizations, refill prescriptions and access their member ID card. The Mayo Clinic app lets users see their upcoming appointments and lab results, view X-rays and read X-ray reports, and communicate

with their physician through a secure portal, among other things.

John Wald, MD, a neuroradiologist and medical director for public affairs and marketing for Mayo, sees a number of advantages of using Touch ID. “The ability to simply place your thumb on the initiation button and allow for entry into the system is a huge advantage,” he says. “In an era where as a professional you have five to 10 different passwords and you have to rotate them every few months, to have one unique ID point—your thumbprint—that allows access is a huge step forward.” He says he and other physicians use it to access Mayo’s electronic health record system on their mobile devices.

Wald believes this is just the beginning for biometrics. “I do think we’ll see more and more of this in the health care field and in all fields as we look to protect patient and personal information.”



# DRESS DECODE

**W**hat you wear can affect your relationship with patients. But what you should don each day seems to depend on where you work and what you do.



So say researchers from the University of Michigan, who reviewed 30 published studies to examine the influence of physician attire on such things as patient trust, satisfaction and confidence. They found that patients preferred formal attire (suits) or white coats in 21 of the studies. That preference was strongest among older patients and those in Europe and Asia. In the studies involving procedural specialties, however, patients either preferred their doctors wear scrubs or had no preference. And in the studies involving intensive care and emergency medicine, patients didn't seem to have a preference.

In an interview published online, lead author Christopher Michael Petrilli, MD, said the findings generally supported his team's thesis—that if physicians' attire matched patients' preferences and expectations, it would improve the overall patient experience. "Doctors of either gender in suits, or a white coat, are more likely to inspire trust and confidence," he noted. "But fashion takes a back seat when it comes to emergency, surgical or critical care, where data show clothes don't matter as much—and patients may even prefer to see doctors in scrubs."

In defense of his fashion-focused research, Petrilli said, "As physicians, we look for evidence-based solutions in our clinical practice. Similarly, we should employ the same ideals when we decide what clothes to wear when seeing patients."

The study, "Understanding the role of physician attire on patient perceptions: a systematic review of the literature—targeting attire to improve likelihood of rapport (TAILOR) investigators," was published in *BMJ Open* in May.

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Several years ago, Carrie Parente, MD, experienced an event no physician ever wants to have happen: A patient left her practice because he felt his privacy had been violated. The man had come to her to be treated for clinical depression. He had suffered his whole life but had kept quiet about his condition, not wanting anyone in his family, at work or in the community to know about it. After each visit, he paid Parente in cash (she doesn't bill insurers in her practice). "He didn't even want to write a check that could be traced back," she recalls.

When he was given a prescription, he took it to a pharmacy that wasn't the one he usually used and paid cash. One day, he came to her and told her his health insurer had sent him a letter that mentioned his diagnosis of depression. "He said, 'How could they have possibly known? I hadn't spoken to anyone about it. I paid cash for everything. How could this have happened?'" Although Parente assured him that she had not released the information, he left her practice.

Parente doesn't know for sure, but she suspects the pharmacy may have sent the prescription information to the patient's pharmacy benefit manager, even though

the patient paid in cash. "It's the only possible link," she says.

#### Cause for concern

Concern about patient information falling into the wrong hands has been growing, and with good reason. Last year, several large-scale cyberattacks made headlines. One resulted in exposure of the names, birthdates, member ID/Social Security numbers, addresses, phone numbers, email addresses and employment information (but not medical records or financial

information) of more than 70 million customers of Anthem, the second-largest health insurer in the United States. Another exposed the financial and medical data of more than 11 million customers of Premera Blue Cross, which does business in Alaska and Washington.

Researchers from Kaiser Permanente and Stanford University who examined U.S. Department of Health and Human Services data found that the number of breaches of information protected by federal privacy laws affecting 500 or more individuals increased from 214 in 2010 to 265 in 2013. Of the 949 total breaches that occurred over the four-year period (involving 29.1 million records), most were the result of theft; only about 10 percent were the result

of hacking. The findings were published in the April 14, 2015, issue of *JAMA*.

In an accompanying editorial, David Blumenthal, MD, from The Commonwealth Fund and Deven McGraw, JD, of the Washington, DC, law firm Manatt Phelps and Phillips, expressed concern about organizations not following best practices for securing their data. They noted that "if patients have concerns that their digitized personal health information will be compromised, they will resist sharing it via electronic means, thus reducing

# PROTECTING PATIENT PRIVACY

Some in the behavioral health community are concerned about the state's **EHR mandate**.

BY KIM KISER



its value in their own care and it's availability for research and performance measurement."

In Minnesota, much of the concern about the privacy of health information has come from the behavioral health community, and most of their concerns center around the use of interoperable electronic health records (Parente maintains paper records in her practice). Last February, at a House Civil Law and Data Practices Committee hearing about data privacy in health care, a number of therapists, psychologists, psychiatrists and patients, along with a handful of privacy advocates, asked for a repeal of a 2007 Minnesota law that required all hospitals and health care practitioners to use an electronic health record (EHR) system that allows for secure sharing of information between providers by January 1, 2015. Several bills exempting certain providers from the mandate were introduced. One that exempts one-person practices and those that do a cash-only business was passed into law. (Those who did not comply with the January 1 deadline were not penalized.)

"Privacy is the foundation of the work psychotherapists do," Stephen Huey, PhD, a Minneapolis psychologist, told the committee. He cited a survey of mental health professionals conducted in January by another Twin Cities psychologist, Richard Sethre, PsyD, that found 43 percent of the more than 650 respondents were "extremely" concerned about the confidentiality of information in EHRs.

**Countering the fear factor**

Diane Rydrych, a Department of Health official who oversees health information technology use in Minnesota, understands the trepidation of many of those who testified. "Data security is something we have to always be thinking about, whether it's within a health care organization or a retail organization or a banking organization," she says. But she points out that many ongoing misperceptions about interoperable EHRs came out during those discussions—specifically, that patient information could be accessed over the



Internet and that it would be shared with the state.

"I think there's a lot of confusion about what health information exchange means," she says. "If it's done securely between a hospital and a clinic using secure email, it doesn't involve putting information on the Internet." As for the state's involvement, she says the Department of Health's role is simply to certify organizations that provide health information exchange services, and to support providers in understanding and meeting the requirements of the law. "We're just involved in making sure they meet Minnesota's privacy and security and other legal requirements," she says. "We do not have access to any of the information that is exchanged between providers."

Rydrych says electronic records are in many ways more secure than paper records, as access to electronic records can

be restricted to those who need specific information to do their jobs—for example, members of a patient's care team or

those who bill and receive payment for services. "If someone uses an EHR, they leave digital finger prints when they view a record, and there's an audit trail so you can see when someone has accessed information who is not part of the care team and should not have access to it," she explains. Requiring the use of passwords and pin numbers and data encryption further ensure security. "Those are best practices that every provider organization should follow," she says.

**Furthering safeguards**

Trisha Stark, PhD, a practicing psychologist and chair of the Minnesota Psychological Association's EHR task force, has been working to educate members of the behavioral health community about EHRs. A solo practitioner, Stark uses an interoperable system in her own practice. She also serves as an alternate member of the



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Department of Health's eHealth Advisory Committee and is co-chairing an effort with the health department and Stratis Health to assist members of the behavioral health community in complying with the state's mandate.

Stark created a website, MNBH-community.com, where providers can find information about systems that suit their needs, fit their budgets and meet the state's requirements. There's also information about a zero-percent-interest loan program for purchasing EHRs.

She admits there have been concerns about some EHR systems sharing information more widely than thought. For



**“Data security is something we have to always be thinking about.”** – DIANE RYDRYCH

instance, information a clinician intended to share only with a patient's primary care physician may unknowingly be available to physicians in specialty clinics.

She says discussions at the national level are addressing some of those concerns. One idea that's being promoted is “data segmentation” (labeling or tagging health information, so as to allow patients to share only parts of their record). “That would provide greater assurances that our data is more private for our patients, especially when it comes to their psychotherapy records and substance abuse records,” she says.

Stark adds that the federal Health Insurance Portability and Accountability Act already provides safeguards that people may not be aware of. For instance, a rule enacted in 2013 allows individuals who pay with cash to instruct clinicians to not share information about their treatment with their health plan. In addition, the law allows clinicians to keep certain types of information private and stored separately from the medical record. This includes psychotherapy notes. In order for those notes to be shared with another clinician, the client must authorize their release. “The idea is to be more circumspect with how we share information so it does protect privacy more for our patients,” she says.

Given that all hospitals and nearly all clinics in Minnesota have EHRs, Stark says behavioral health clinicians eventually will have to find ways to share relevant information, especially if they wish to participate in accountable care organizations. “I think those providers who are not part of the EHR world will be out of the health care system in terms of referrals and communication and things like that,” she says. “I think market forces will force them to adopt EHRs.” MM

Kim Kiser is an editor of *Minnesota Medicine*.

## MAKING USE OF STATE LAW

When it comes to protecting patient privacy, Minnesota's patient consent law is stronger than the federal Health Insurance Portability and Accountability Act's requirements. Diane Rydrych, who directs the Minnesota Department of Health's Health Policy Division, says in Minnesota, patients must give consent any time protected health information is shared, whether electronically or on paper.

She says the Department of Health worked with privacy advocates a number of years ago to develop a standard consent form that allows patients to specify in a very detailed manner what type of information they wish to share and who they wish to share it with. “As a patient, I can say I only want my immunization information shared or I only want my health history shared, but I don't want my mental health records shared, or I only want to share them with a certain provider. It allows a lot of granularity with regard to content,” she explains. (Rydrych adds that patients must indicate in two places on the form whether they want to share information related to mental health or chemical dependency.)

The challenge, she says, is getting organizations to use the form. (It is available at [www.health.state.mn.us/divs/hpsc/dap/consent.pdf](http://www.health.state.mn.us/divs/hpsc/dap/consent.pdf).) “Some of the big systems of care have set it up so you sign your life away when you go in for your first appointment—that you give permission to share with anyone,” says Trisha Stark, PhD, a practicing psychologist and chair of the Minnesota Psychological Association's EHR task force. She says she has been working with the association to educate the behavioral health community about the consent form. “I think there's more clinicians can do to teach patients to be better consumers and how to use consent laws to protect their own privacy.”—KK



# WHAT HAPPENS WHEN THE DOCTOR NEEDS A DOCTOR?



Physicians care for the health of others, but sometimes they may neglect their own health.

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BY HOWARD BELL





A Bloomington occupational medicine physician's DEA number is stolen and used to forge 69 narcotic prescriptions for 25 fake patients at 23 pharmacies around the state before authorities finally stop the crime ring responsible.



A St. Louis Park psychiatrist discovers someone is calling in fraudulent prescriptions using her DEA number.



A Virginia, Minnesota, physician discovers someone has used his identity to file a fraudulent tax return in order to steal his income tax refund. The same thing happens to an emergency physician at Olmsted Medical Center and to physicians at Mayo Clinic, Children's Hospitals and Clinics of Minnesota, HealthEast and elsewhere.

## IDENTITY THEFT IS ONE OF THE FASTEST GROWING CRIMES IN THE NATION ACCORDING TO THE U.S. DEPARTMENT OF JUSTICE, AND PHYSICIANS ARE AMONG THE VICTIMS.

Their DEA numbers, medical license numbers, Social Security numbers and National Provider Identifier (NPI) numbers are used by those forging prescriptions for controlled substances and billing Medicare for services never provided. Their personal information is taken by those committing tax fraud.

Some say physicians are targeted because their identifiers are widely disseminated. Personal information and DEA numbers are stored on multiple computers in health systems. Medical license numbers and NPI numbers are used by clinics, hospitals, labs, medical supply companies and insurers for billing and payment; in electronic health record systems; and in health plan communications.

Whether or not physicians are uniquely vulnerable, identity theft is occurring all too often. And victims say it's maddening when it does.

## PRESCRIPTION FOR TROUBLE

Physicians find out their DEA number has been stolen when they start getting calls from pharmacies about suspicious prescriptions. DEA numbers can fall into the wrong hands in a number of ways, according to Dulce Foster, JD, who helps physician victims of identity theft and chairs the White Collar and Regulatory Defense Department at Fredrikson and Byron, PA in Minneapolis. "Patients stealing prescription pads is the low-tech way," she says. "It happens sometimes, but it's not so common because most physicians are pretty good about protecting their prescription pads."

Sometimes thieves steal laptops. Sometimes they hack into clinic, insurer and pharmacy databases to get DEA numbers and other physician identifiers. But Foster says in her experience "physician identity thefts are often inside jobs."

Employees throughout the health care system have access to DEA numbers. Some may want the information for themselves. (Minnesota Board of Pharmacy Executive Director Cody Wiberg

# PRESCRIPTION FRAUD

## HOW TO PREVENT IT

- E-prescribe** whenever possible to reduce the risk of paper prescriptions being stolen.
- Write prescriptions clearly and spell out numbers** to reduce risk for forgery.
- Keep paper prescription pads in your pocket or locked in your office.**
- Enroll in the Board of Pharmacy's Prescription Drug Monitoring Program (PMP)** at [Minnesota.pmp@state.mn.us](mailto:Minnesota.pmp@state.mn.us). Monitor the list of all Schedule II-V controlled substances that have been prescribed each year to make sure they're all legitimate. If you see a problem, notify the PMP at 651-201-2836.
- Inform staff that you periodically check the PMP.** "This can have a chilling effect on anyone tempted to commit insider physician identity theft," says Dulce Foster, JD, who works in the White Collar and Regulatory Defense Department at Fredrikson and Byron in Minneapolis.

## WHAT TO DO IF IT HAPPENS TO YOU

- Call the DEA Minneapolis office** at 612-344-4100.
- Notify local law enforcement.** Don't be surprised if they don't investigate. Yours may be an isolated incident. But passing forged prescriptions is a felony, and at least they'll have the information to connect the dots to similar fraud.
- Report the theft to the Federal Trade Commission (FTC) Identity Theft Clearinghouse** at 877-438-4338 or [www.ftc.gov/idtheft](http://www.ftc.gov/idtheft) (click on "Create identity theft report"). You'll receive a reference number for your case. The complaint database is available to more than 2,000 federal, state and local law enforcement agencies that use the information to detect patterns of fraud when investigating identity thieves. The FTC doesn't investigate individual complaints, says Steve Toporoff, the FTC's director of privacy and identity protection, but, he says, "Clearing your name is a good reason to file a complaint with us. We'll send you an identity theft affidavit that will help you resolve any legal liabilities you might have because of the theft."
- Notify the PMP** at 651-201-2836.
- Notify the pharmacy** where the suspicious prescription was filled.

has seen physicians, pharmacists and other health care professionals use another prescriber's name and DEA number to forge prescriptions to get drugs to feed their addiction.) Others may get a DEA number for outsiders, Wiberg says, noting that identity theft rings offer to pay for the information.

Once a thief has a DEA number, the rest is easy. "Anyone with a computer and a decent printer can generate fake prescriptions," Wiberg says. "Medical-grade security paper is available at office

Bloomington occupational medicine physician John Sandness, MD, uses nonsurgical and nondrug methods to treat back pain. So he was surprised to return from vacation in August 2012 to find a phone message from a pharmacy asking him to verify a questionable

## A CASE OF

prescription for narcotics. By the time he returned the call, the prescription had been filled.

Over the next few days he received several more such calls. Sandness called the police about the prescriptions written using his DEA number and enrolled in the Prescription Monitoring Program (PMP). Sandness had never used the PMP before. Once he registered, he saw 20 forged prescriptions using his DEA number. "Pharmacies filled two-thirds of the prescriptions without phoning me to verify," he says.

Over a two-month period, 69 forged prescriptions were filled at 23 pharmacies around the state. The prescriptions were always the same: 180 30-mg oxycodone tablets, 15 Fentanyl patches, 75 mcg/hr and 60 2-mg alprazolam tablets.

After one forgery incident at a suburban Twin Cities pharmacy, Sandness notified local police, who retrieved surveillance camera footage showing the suspect. Since Sandness couldn't identify the suspect and the suspect used a stolen identity, the police couldn't pursue the case. When he asked a couple of the pharmacies that are part of big chains if they could send out email alerts warning other pharmacies, he was told their computer systems couldn't do that.

As the forgeries continued to mount, a "diversion investigator" from the DEA's Minneapolis office interviewed Sandness.

With help from several pharmacists and the police, three arrests were made in Perham, Mendota Heights



supply stores.” No paper is needed to forge Schedule III, IV and V controlled substance prescriptions because they can be phoned in by someone claiming to work at a clinic, he says.

Foster had a case in which a nurse who had chronic pain and was addicted to painkillers phoned in Vicodin prescriptions. She used the name of a patient at her clinic who was also a friend and agreed to pick up the prescriptions. “Theft of DEA numbers has been a problem for years,” Foster says. “It’ll stay a problem as long as people are addicted to narcotics.”

and Forest Lake, Minnesota. The fraud ended. “It was a fairly sophisticated drug ring that hit a pharmacy once, then moved on to a different community,” Sandness says. “They knew local law enforcement has limited resources and could only investigate crimes in their jurisdiction.”

## PRESCRIPTION FRAUD

In order to get patient information for their fraudulent prescriptions, the culprits stole people’s wallets and purses to get IDs and insurance cards, in one case stealing a woman’s purse at an outdoor music festival. They printed and forged prescriptions on 8 ½ X 11” thermal safety paper, sometimes used for legitimate prescriptions and available at office supply stores. Sandness’ Minnesota medical license number was on the forged prescription sheets, even though that number is not on his real prescription pads.

Sandness doesn’t know how they got his medical license number. The thieves changed one digit of his phone number on the forged prescription sheets, Sandness thinks, to make it harder for pharmacists to call him to verify the prescription. The wrong phone number tipped off some pharmacists that the prescription might be a forgery.

He also does not know how they got his DEA number. He rarely writes prescriptions and always keeps the pads locked in his office. He suspects it might have happened when he had a company shred a lot of documents after he moved his office. Among the documents were prescription pads with his former clinic address. Someone working for the shredding company could have taken one of the slips. The forgeries started less than two weeks later.

He says the “couple dozen” hours he spent stopping the fraud were difficult and frustrating, but worth it. “I felt violated,” he says. “I feared my reputation might be affected, that people would think I’m irresponsible with narcotics. Mostly I wanted to make sure these guys got caught.”—HB

## BOGUS BILLING

In 2010, a California crime ring used stolen physician identifiers to bill Medicare for more than \$100 million in claims for services never provided at 118 fake clinics in 25 states. Minnesota wasn’t one of them, but such fraud is still happening, according to the Centers for Medicare and Medicaid Services.

Knowing a physician’s NPI number isn’t enough to bilk Medicare, but it’s one identifier fraudsters need in order to do so. Medicare scammers also need physicians’ names, dates of birth, Social Security numbers and employer identification numbers. Thieves can simply access physicians’ medical license numbers and NPI numbers, both of which are public, to obtain such information. They then can pair that information with information about real Medicare patients,

## MEDICARE FRAUD

### HOW TO PREVENT IT

- 0 **Review your Medicare remittance notices.** Look for services you never provided, payments you never received or patients who aren’t yours.
- 0 **Check Medicare’s Provider Enrollment Claim and Ownership System (PECOS)** (<https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>). Make sure the clinics, hospitals, health plans and medical supply services associated with your name are accurate.
- 0 **Encourage your patients to review their explanation of benefits** to make sure the services listed are services they received.
- 0 **Encrypt sensitive information**, especially on laptops, which are easily stolen.
- 0 **When applying for an NPI number, don’t enter your Social Security number, medical license number, income tax ID number or employer ID number.** This information is not required to receive an NPI number.

### WHAT TO DO IF IT HAPPENS TO YOU

- 0 **Notify the Health and Human Services Office of Inspector General** at 800-447-8477 or [HHSTIPS@oig.hhs.gov](mailto:HHSTIPS@oig.hhs.gov).

whose identities they have also stolen in order to bill for services never provided.

Sometimes Medicare fraud rings get caught when CMS flags suspicious reimbursement claims. (CMS recently launched a fraud-prevention system that screens all Medicare claims before they're paid and flags suspicious ones, much like credit card companies do when there's suspicious activity.) In one case, a dermatologist's identifiers were used to bill for heart tests. In another, an otolaryngologist's identifiers were used to bill for pregnancy ultrasounds.

## TAX FRAUD

### HOW TO PREVENT IT

- 0 **File as early as possible** (before the thieves do).
- 0 **Consider subscribing to an identity protection service** such as Life Lock, Identity Guard, Identity Force or Trusted ID.
- 0 **Shred sensitive documents** and protect your Social Security number as much as possible.
- 0 If you think you may have been victimized, **call the IRS Identity Protection Specialized Unit** at 800-908-4490.
- 0 **Purchase identity theft insurance.**

### WHAT TO DO IF IT HAPPENS TO YOU

- 0 **Call the FTC Identity Theft Clearinghouse** at 1-877-438-4338 or go to [www.ftc.gov/idtheft](http://www.ftc.gov/idtheft) and click on "Create identity theft report." You'll receive a reference number for your case. Law enforcement and the IRS use the FTC's database of complaints to look for patterns of fraud. The FTC doesn't investigate individual cases. A printed version of your complaint serves as your identity theft affidavit that helps clear you of any financial liability.
- 0 **Call the Social Security Administration's fraud hotline** at 800-269-0271 to report that your number has been fraudulently used.
- 0 **Have the IRS issue you a PIN** or create your own [www.irs.gov/Individuals/Electronic-Filing-PIN-Request](http://www.irs.gov/Individuals/Electronic-Filing-PIN-Request)
- 0 **Go to Experian.com/fraud** and put yourself on a 90-day credit fraud alert. Experian notifies Equifax and TransAmerica, the other two major credit reporting agencies.

In a handful of cases, physicians have knowingly allowed scammers to use their identifiers in exchange for money. In the vast majority, however, physicians don't know their identity has been stolen until CMS investigates them for overpayment or the IRS investigates them for failure to pay taxes on Medicare income.

Spokesperson Tony Salters says CMS routinely investigates when a physician reports fraudulent use of an NPI number, but they haven't seen an increase in such thefts in recent years.

The AMA has asked CMS to stop making NPI numbers public and to prohibit insurers, medical supply companies and government agencies from routinely using physician Social Security numbers. Even if that happens, securing the information will be difficult because it's already so widely used. (CMS recently made the decision to no longer display NPI numbers on the reports of

In March, Virginia, Minnesota, physician Dr. V, who requested anonymity, received a letter from the IRS telling him they had received his tax return and that some forms and schedules were missing. "I knew there was a problem because I hadn't submitted my return yet," V says.

## A CASE OF

Both Dr. and Mrs. V's Social Security numbers and birth dates were on the fake federal income tax return. "We have no idea how they got this information," V says. "We shred everything. We don't give our Social Security numbers to anybody. Maybe it was a disgruntled IRS employee. My Social Security number is on my medical license, but my wife's isn't. It's on my Medicare card, too, but my wife doesn't have Medicare." After receiving the IRS letter, the Vs promptly called Life Lock, an identity protection service they subscribe to. "They told us they hadn't seen anything suspicious on their end," V says.

The Vs electronically filed their return the day after they received the letter only to have it rejected. Like all victims of electronic tax fraud, the IRS instructed the Vs to file a paper return, along with the IRS identity theft forms that are required in all such cases. The IRS's tax fraud department told them to call the Federal Trade Commission (FTC), which keeps track of tax fraud cases so they can look for patterns of theft and victims can testify against the perpetrators if they're ever caught.



the payments made and gifts given to physicians and teaching hospitals by medical device and drug makers, as required by the Sunshine Act.)

## PHONY FILING

Tax fraud is a huge challenge facing the IRS. From 2011 to 2014 it stopped 15 million suspicious tax returns worth more than \$50 billion in fraudulent refunds. In 2013, the IRS paid \$4 billion in fraudulent tax refunds; it paid \$4 billion the year before that. The scale and scope of these crimes have grown substantially in recent years, according to the U.S. Department of Justice.

Physicians aren't the only ones to have their tax refunds stolen; but in recent years more of them have been victims, according to the AMA. Although the exact number isn't known, several state

The IRS also told them to notify the Social Security Administration, the Minnesota Attorney General, the Minnesota Department of Revenue and the local sheriff. The Attorney General recommended that they also notify their bank. The FTC told them to notify Equifax, one of three major credit reporting agencies,

# TAX FRAUD

which would then automatically notify the other two agencies about monitoring the V's financial activity for anything suspicious.

The IRS will send the Vs a PIN number to use for their 2016 tax return. The PIN number is an extra layer of security that prevents someone else from filing a fake return using only their names and Social Security numbers.

The fraudsters didn't succeed in hijacking the V's refund. Even if they had, the IRS always pays the victim their refund. Mrs. V, who recently retired after working 25 years at the acexperiocounting office that prepares their tax forms, says the incident wasn't particularly stressful for her because she'd been a tax accountant for so long. But she says the whole thing weighed heavily on her husband.

"I can understand why people feel personally violated," V says. "It could be as long as a year before we get our refund. I'm an older physician, so that's not such a problem, but this kind of thing could put a strain on the finances of a young doctor with a family waiting for that refund."—HB

medical societies reported that the number of doctors, dentists and nurses targeted increased significantly in 2014. Some suspect the increase was related to large security breaches such as the Anthem/Blue Cross mega-hack in 2014.

Although Minnesota physicians have been less vocal than physicians in other states, the Minnesota Medical Association last year heard from about two dozen who had been affected. This year, Mayo Clinic sent reminders to its staff about the potential for identity theft during the tax season. They also sent communications with specific steps to follow in the case of suspected or proven theft.

Sometimes insiders steal Social Security numbers in order to file the phony tax refunds themselves, says Steve Toporoff, the FTC's director of privacy and identity protection. Sometimes outsiders willing to pay for information approach clinic and insurance company employees.

Once thieves have a person's name, date of birth and Social Security number, they can electronically file their taxes, fabricating income and deductions to generate a return. They direct the IRS to deposit the refund into a debit account. They then use their debit card to withdraw the money from an ATM.

Victims are unaware of the theft until they try to file their tax returns and receive a letter from the IRS notifying them that someone has already filed using their Social Security number. They are instructed to call the IRS or go to its website and confirm that they did not file the return referenced in the letter.

The IRS issues all tax fraud victims a personal identification number (PIN), an extra layer of security that can make it harder for someone else to submit your return. Even if you haven't been a victim, you can still get a PIN.

In June 2014, the AMA asked the IRS to prohibit insurers, health systems, medical supply companies and government agencies from routinely using physicians' Social Security numbers in order to make it harder for identity thieves to get their hands on them. Thus far, that hasn't happened.

The good news is that those who've been victims of tax fraud do get their refund, although it will be delayed and they will be required to fill out extra forms.

## TACKLING DEA NUMBER THEFT

The Twin Cities Medical Society (TCMS) recently formed a work group to address the DEA theft problem. TCMS plans to bring together representatives from the Board of Medical Practice, Prescription Monitoring Program and the Attorney General's office, as well as physicians themselves to seek solutions.

One of those participating in the work group is St. Louis Park psychiatrist Marie Casey Olseth, MD, whose DEA number was stolen last year and used to call in 30 bogus prescriptions for alprazolam (Xanax). "Locking up prescription pads, encouraging patients to keep their prescriptions stored out of view, and using controlled substance contracts when appropriate are all worth doing, but they're inadequate to shore up the cracks in the system," she says.



Olseth believes the state needs a law limiting the quantity of a controlled substance that can be phoned into pharmacies or not allowing them to be phoned in at all. “Phoning in 90 2-mg alprazolams with two or three re-fills should clearly be illegal,” she says. “You’d think such an excessive dose and quantity would raise suspicions at a pharmacy, but it often doesn’t.” In her case, five different pharmacies filled bogus prescriptions.

Olseth also would like to see a requirement that any person picking up a controlled-substance prescription present a government-issued photo ID. “You need one to buy anything containing pseudoephedrine,” she says.

Allowing e-prescribing of such drugs is another idea some are considering. Minnesota’s original e-prescribing law did not allow e-prescribing of controlled substances, but the Board of Pharmacy asked the Legislature to amend the law to allow it. “It’s up to the Department of Health to interpret and implement the section of statutes that requires e-prescribing,” Wiberg says. Based on how the law now reads, he says “e-prescribing controlled substances should already be the norm in Minnesota.”

For now, many view the Board of Pharmacy’s Prescription Monitoring Program (PMP) as the best first step for stopping DEA number theft. Physicians can check the PMP to determine if their DEA number has been used by someone trying to obtain fraudulent prescriptions—something Olseth says many aren’t aware of. Two bills introduced at the Legislature this year would have made prescriber enrollment in the PMP mandatory. Neither passed. Wiberg says the proposal will probably be reconsidered next year as part of a larger multi-agency bill designed to address prescription drug abuse.

John Sandness, MD, the Bloomington occupational medicine physician whose DEA number was stolen, started using the PMP soon after. He says it’s helpful but he would like to see it have the capability to alert pharmacists if there’s a pattern of abuse with a DEA number.

Practical and legal obstacles make flagging DEA numbers easier said than done, however. “We can’t flag DEA numbers that may have been used to forge prescriptions,” Wiberg says. “The PMP isn’t set up that way, and even if it was, patients who had legitimate prescriptions issued by the prescriber with that stolen DEA number might not be able to get their prescriptions filled.” Nor can names of patients be flagged because people forging prescriptions often use a legitimate patient’s identity. “We would

end up flagging a completely innocent person as a forger,” he says. Nor would it help to require pharmacists to report forged prescriptions to the PMP. “Most of the time they dispense a forged prescription because the forgery is good enough to fool them,” Wiberg says.

Another reason flagging won’t work is because pharmacies sometimes accidentally select the wrong prescriber from a drop-down list when entering the prescription into their computer system. If that error isn’t caught before the prescription is dispensed, the prescription gets posted in the PMP under the wrong prescriber’s name.

Thus far, the physicians whose DEA numbers have been used by prescription forgers haven’t had much help from pharmacies. When Olseth asked for help setting up a sting to catch those who were using her DEA number, she was told the pharmacy chain’s corporate policy is to not participate, understandably concerned that

such operations could scare away customers or prove dangerous. Sandness asked one pharmacy chain if it could program its computers to alert all of their stores whenever a stolen DEA number is used to fill a prescription. “I came away with the impression that they weren’t able to do that,” he says.

Sandness and Olseth believe there needs to be a way to report DEA number theft and get someone to do something about it. “We need one agency or organization to be the go-to contact when your DEA number gets stolen,” Olseth says. “No one should have to endure the endless phone tag, lack of support from authorities, and the turfing off of the problem to someone else.”

Because so many agencies and organizations keep physician identifiers on file, it makes it hard for physicians to protect themselves from identity theft, beyond taking the obvious steps like locking up prescription pads and not giving out Social Security numbers. And as long as their information is stored in so many different places, physicians will need to be more vigilant than ever in safeguarding their identities. **MM**

Howard Bell is a medical writer and frequent contributor to *Minnesota Medicine*.





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# Listening to the heart

When instinct tells you there's more to the story

BY NELS DANIEL LEAFBLAD

It was one week into my family medicine rotation at a clinic in St. Paul when the resident I was working with asked me to do a standard 6-month well-child check in the next room.

Anna was all smiles when I walked through the door. I introduced myself to her mother, Whitney, and found myself smiling, too. For the next 10 minutes, I went through the expected developmental milestones and addressed Whitney's concerns about her daughter.

Anna had been born at full term without any complications during pregnancy or delivery. She was feeding well and gaining plenty of weight. She was a good sleeper, with the exception of consistently waking in the early hours of morning, causing mom to unenthusiastically get up to feed her. Things were checking out just

fine, and I thought, "Man, this is going to be a nice, easy visit."

Then I asked how things were going at home for mom and dad.

I knew Whitney was young—19 to be exact—and that she had a disability that limited her conversational skills. But she was well-informed and clearly knew what to look for in her developing baby. And her adoration for her daughter was inspiring.

The circumstances that Anna was born into were not ideal. Whitney had only met Anna's father two months before the baby was conceived. Early on, dad had been excited and showed promise for being a caring and supportive father, making it to every prenatal visit, asking good questions and staying involved.

But this day I learned that things had changed after Anna showed up. Whitney's boyfriend had changed jobs and was becoming dissatisfied with the new one. He

had stopped showing interest in Anna, insisting that Whitney take care of everything "baby." He refused to change diapers, get up at night, feed the baby.

As she began describing the father's refusal to even hold Anna, Whitney broke into tears. Things were taking a toll on her. With the exception of getting a few hours of respite each week when her mom would babysit, Whitney was dealing with her baby 24/7, essentially all on her own. She had no car. She was stuck at home. Dad was out drinking.

She cried even harder when she described her own childhood without a father. All Whitney knew about her dad was that he was in prison for doing something bad. She described how she would lie to her friends, telling them that her dad had died in order to spare herself the embarrassment of explaining that he was locked up. Her biggest fear was that Anna would grow up the same way.

My heart was heavy. Had I been watching this scene play out on a screen, I too would have had tears in my eyes. But I wasn't watching this on a movie screen. I was in the room, three feet away from Whitney, searching for what to say. Maybe all she needed to hear was, "I am so sorry" or "I can't imagine what you must be going through." I said those words, and I meant them.

But I knew it could not end there. She needed help.

What do you do when a dad refuses to hold his new baby? How do you comfort a mother who fears she will have to go it alone? Outside the room, my preceptor and I discussed how we were going to address the situation. Whitney needed support and a place to rest. At home alone with Anna all day, every day, while her boyfriend was at work or out at the bars, she was struggling.

After consulting with our clinic social worker, we made a plan to connect Whit-

## How do you comfort a mother who fears she will have to go it alone?

ney with a single-mother support service. We confirmed that she and Anna were both safe at home. The next step was getting Whitney the assistance she so desperately needed, with a plan to follow up with her to see how things were progressing.

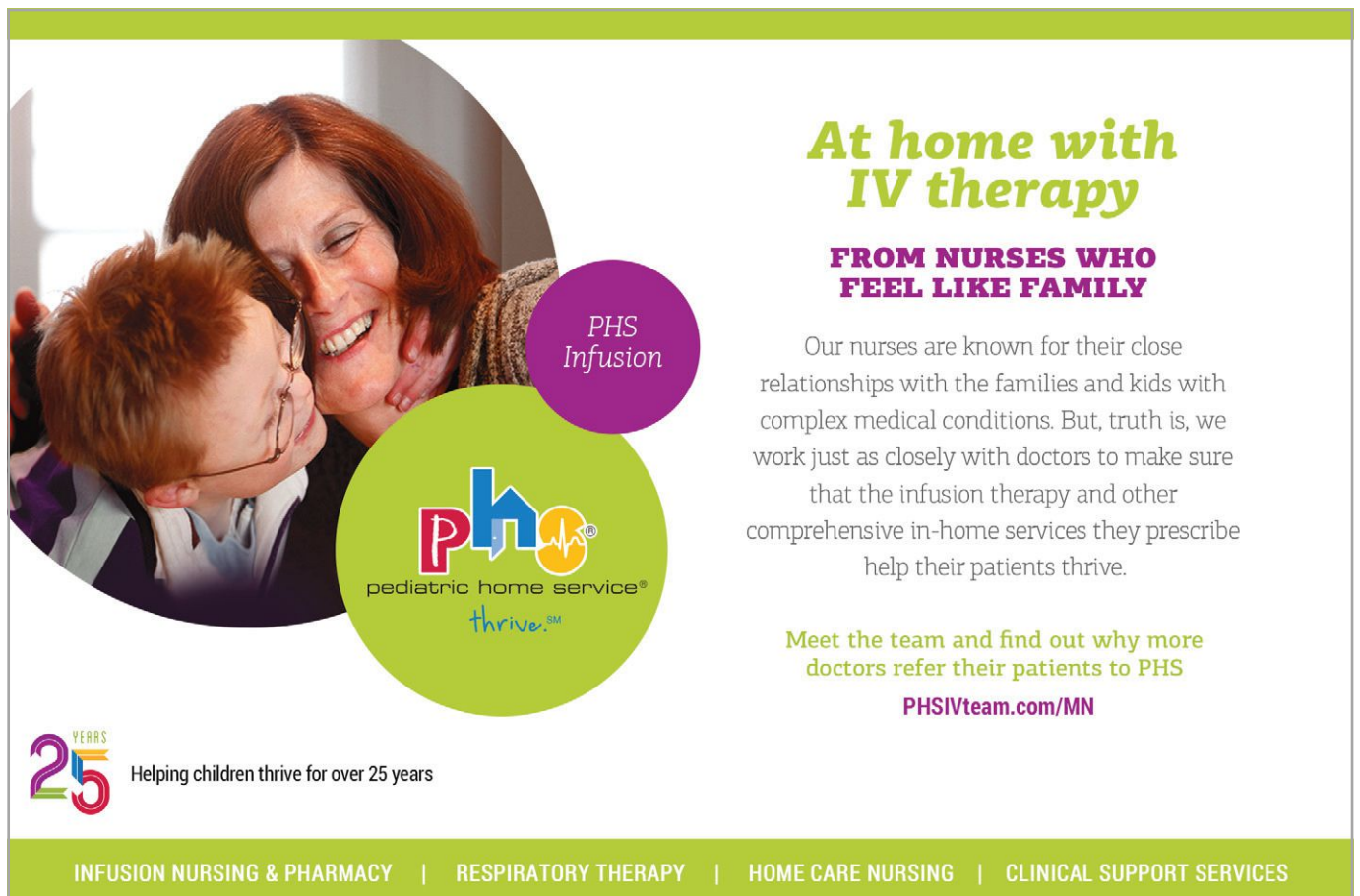
Reflecting back on the visit with Whitney and Anna, I see that I could easily have missed out on the opportunity to hear Whitney's story. It was a well-child check. I could have focused all my attention on how Anna was developing without delving into the specifics of Whitney's

relationship with her boyfriend and how she was doing emotionally. I had wanted so much for the situation to be right—for Anna's dad to be a real, loving presence, for Whitney not to bear the entire burden of caring for their child, and for Anna to grow up knowing that she had a dad who loved her and who would be there for her. But the situation wasn't right, and it was important I find that out.

I don't know how everything will play out. I do know that Whitney is a strong young woman who loves her daughter deeply.

As members of the health care team, we have the privilege and opportunity to usher in change for patients, their families and the broader community. What we choose to do—or not do—in the process of healing and calming the body, mind and spirit of our patients can have lasting significance. **MM**

Nels Daniel Leafblad is a third-year medical student at the University of Minnesota.



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## OIL AND WATER

# Opposing parties make for challenging session

BY DAN HAUSER

**W**ith each party controlling a chamber, the 2015 legislative session proved to be contentious. And that turned out to be problematic for physicians and their patients.

In the end, several of the MMA's top priorities, including prior authorization and the Medicaid payment bump, ended up on the cutting room floor. The House and Senate did, however, pass a \$15 billion Health and Human Services (HHS) budget bill.

With a nearly \$2 billion surplus in the state's coffers, many assumed the session would go more smoothly. However, House Republicans, Senate Democrats and Gov. Mark Dayton butted heads right up until the final days.

After it was over, the House Republicans celebrated that they were able to finish their work on time and pass the needed budget bills to keep the state running. The Senate Democrats took credit for stopping some of the drastic budget cuts proposed by the House and finishing on time. However, Gov. Dayton was not happy with the final version of the E-12 education bill and vetoed it. A special session to resolve education funding will likely be brief and take place before June 30.

"From the MMA's perspective, it was at best a mixed session," says MMA President Donald Jacobs, MD. "We are pleased that we were able to get the interstate compact passed, increase funding for loan forgiveness and keep the provider tax repeal on schedule. Those are three of our top six priorities. But certainly, we're disappointed that we couldn't get bills passed to reform prior authorization and increase Medicaid reimbursement."

## MMA priorities for the 2015 session:



### PRIOR AUTHORIZATION REFORM.

The MMA's top priority, reforming medication prior authorization, failed to gain the necessary support. Although our bill passed through four committees in the Senate with overwhelming backing, it never

received a hearing in the House. Language that was included in the Senate HHS budget bill was removed on the last day of the conference committee because it was not a part of the final compromise between the Senate and House. The House listened to the health plans' argument that the bill would significantly hamper their ability to control costs. Senate author Melisa Franzen (DFL-Edina) made it clear that she intends to pursue the issue over the interim and will bring the bill back next year. The MMA intends to build a media and grassroots campaign over the summer to ensure legislators are hearing from patient groups as well as physicians as to why changes to prior authorization are needed.



### INTERSTATE COMPACT FOR PHYSICIAN LICENSURE.

This measure passed unanimously and was quickly signed by the governor. The compact will allow for a voluntary accelerated process for physicians to become licensed in multiple

states. It maintains states' authority to license and regulate physicians but establishes an expedited process. Minnesota became the eighth state to join the compact, exceeding the threshold number required for the compact to become functional. The states that enact the law first will have a role in establishing the rules for the new process.





accelerating it by one year as part of the debate regarding MinnesotaCare. In the end, the measure did not pass.

**MAINTAIN THE REPEAL OF THE 2 PERCENT PROVIDER TAX.** The 2 percent provider tax is still scheduled for repeal on December 31, 2019. There had been efforts to eliminate the repeal in the past—but not this year. In fact, the House proposed ac-



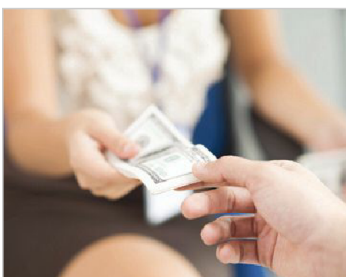
allocated \$1 million per year to fund programs to prepare foreign-trained physicians for residency programs or to practice in another health care profession, and they provided \$1.5 million for additional residency programs. Also included in the budget proposal was language and funding intended to better utilize the skills of foreign-trained immigrant and asylee physicians.

**HEALTH CARE WORK-FORCE.** The final HHS budget bill included an increase of \$2.6 million for loan forgiveness programs for physicians and other health care providers who serve in rural and underserved urban settings. In addition, legislators



reduce the existing tobacco tax on premium cigars and certain types of e-cigarettes, and to remove the automatic inflationary adjustment of the tobacco tax. None of the tax reductions passed.

**E-CIGARETTES AND TOBACCO.** The MMA's priority was to add e-cigarettes to the Freedom to Breathe law, but the effort did not gain traction this session. During tax debates, MMA leaders were concerned with a number of proposals to



promise bill. The HHS bill does call for creation of a 29-member task force that will discuss funding of the state's health care programs, including MinnesotaCare, the future of MNsure, and the

**CONTINUING THE PRIMARY CARE PAYMENT BUMP IN MEDICAL ASSISTANCE.** The Senate HHS bill included a 1 percent increase in Medical Assistance payments for primary care physician services, but it was not included in the final com-

provider tax, and how to ensure that payments rates in the public programs are adequate.

## Other health care bills:



action of the 2 percent provider tax repeal. The MMA opposed the dissolution of MinnesotaCare.

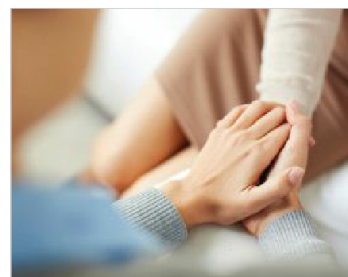
**MINNESOTACARE II.** The House effort to repeal MinnesotaCare and move its participants into MNsure failed. The future of MinnesotaCare will be discussed by a new 29-member task force. Because this did not pass, neither did the accel-



eration of the 2 percent provider tax repeal. The MMA opposed the dissolution of MinnesotaCare.



**HEALTH CARE ACCESS FUND USES.** The final HHS budget bill called for using \$76.7 million from the fund to help pay for the Medical Assistance program over the two-year biennium.



**FUNDING FOR MENTAL HEALTH SERVICES.** Legislators set aside \$46 million for mental health services, including funding for behavior health homes, suicide prevention grants and new beds at the Anoka Regional Treatment Center.



**SHIP FUNDING MAINTAINED AND FOCUS EXPANDED.** Efforts to eliminate the Statewide Health Improvement Program (SHIP) grants failed. In fact, legislators expanded SHIP’s focus and provided grants to improve the health status of

targeted populations at risk for dementia. In addition, lawmakers approved language to transfer savings from SHIP activities to the Health Care Access Fund to be used for health programs.



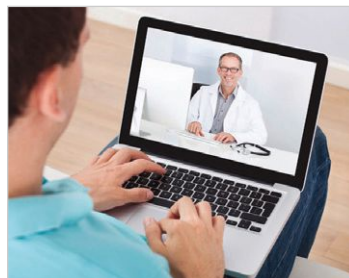
**RIGHT TO TRY.** Gov. Dayton signed into law a bill that allows terminally ill patients access to pharmaceuticals, biological products and devices that have not completed FDA trials. The language states that patients with “a condition or illness

which, to a reasonable degree of medical probability, is not considered reversible and even with the administration of current FDA-approved and available treatments and the administration of life-sustaining procedures will soon result in death” will be allowed to try a drug that has successfully completed Phase 1 of a clinical trial. The bill does not mandate that a physician participate or that a pharmaceutical or device manufacturer make the products available, nor does it require that the patient give written informed consent in order to receive a prescription or recommendation from a physician before they’d be eligible. Although the MMA did not take a position on the bill, it did work with the author on an amendment to provide liability protection for physicians who choose to participate.



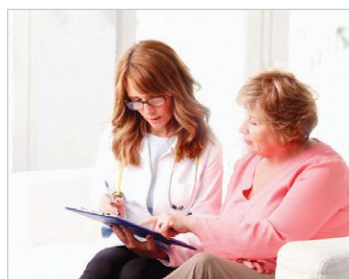
**TRISOMY.** The governor also signed into law a bill that requires physicians to direct patients to specific information on the Minnesota Department of Health website if a prenatal diagnostic test shows that a fetus has a trisomy condition. The Health

Department needs to ensure the information is current and evidence-based, and includes details about life expectancy; expected physical, developmental and social outcomes; treatment options; and contact information for support groups. Earlier this session, the MMA sent a letter to legislators urging caution in adopting bills such as this, as they interfere with the physician-patient relationship.



**TELEMEDICINE.** A bill intended to expand and support the use of telemedicine in Minnesota was included in the final HHS spending bill. The MMA supports the goals of this legislation—

requiring parity for payment of services provided through telemedicine. The Legislature set aside \$344,000 for 2016-17 and \$1.5 million in 2018-19.



**ADVANCE CARE PLANNING GRANT.** Legislators allocated \$250,000 to a “statewide advance care planning resource organization” to develop community-based strategies to encourage conversations on end-of-life choices expressed by patients. This is

an initiative the Twin Cities Medical Society has promoted through Honoring Choices Minnesota.



**VACCINATIONS.** A bill that would have required parents who want their children to be allowed to opt out of the vaccinations required for enrollment in public schools to first consult with a physician on the benefits and risks of that decision cleared its first

committee in the Senate but was not considered in the House. The MMA supported this legislation. Language was included in the final HHS bill that allows pharmacists to administer flu vaccinations to children as young as 6 years of age and all other vaccines to those ages 13 years and older. The MMA testified that the provision would pose risks to continuity of care and the health care home. The MMA also argued that an office visit is critical to monitoring all aspects of a young person’s health.





**ALL-PAYER CLAIMS DATABASE.** A provision to authorize the creation of public use files of summary data from the all-payer claims database was included in the final HHS spending bill. Under this provision, the Department of Health is required to make available to the public de-identified summary data on health care use and spending patterns. The cost is \$483,000 in 2016-17 and \$455,000 in 2018-19. The MMA supported this legislation.



**AUTOPSIES.** A bill that would allow Minnesota families limited objections to autopsies based on their religious beliefs passed both bodies and was signed by Gov. Dayton. If a family objects for religious reasons, an autopsy may be performed only if the coroner or medical examiner determines there is a compelling state interest. The MMA watched this legislation with concern because of its potential to interfere with the practice of medical examiners and coroners.



**MEDICAL CANNABIS.** A bill to offer legal protections for physicians and other health care employees who handle a patient's medical cannabis as part of their employment passed the House on the final day of the session and is expected to soon receive the governor's support. The bill also moves up the date (from July 1, 2016, to January 1, 2016) by which the Department of Health must make a decision about allowing the use of medical cannabis for the treatment of intractable pain.



**SURVIVORSHIP.** The MMA joined with a broad coalition of health care interests, the Chamber of Commerce and others to oppose an effort to roaden the ability of individuals to sue for damages. Under the provision, family members are allowed to pursue legal actions that would "stack" damages for both pain and suffering as well as wrongful death in cases in which a family member has died. Although it was improved dramatically through an amendment in the Senate, the provision did not move in the House. MM



CHANNEL YOUR PASSION

## Join a committee

The MMA is seeking volunteers to serve on its policy committees.

As a committee member you

- influence the MMA's direction,
- acquire new leadership skills, and
- network with physicians who care about the same issues you do.

It is easy and only includes four evening meetings annually. If you can't make a meeting in person, you can also call in.

For specific committee assignments, go online to: [www.mnmed.org/committee](http://www.mnmed.org/committee).

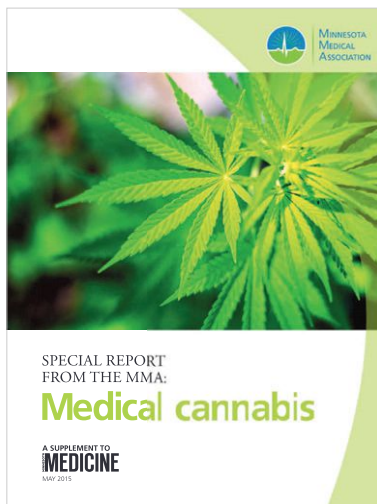
If you are interested in volunteering, send an email to [mma@mnmed.org](mailto:mma@mnmed.org) and indicate the specific committee. An MMA staff person will follow-up with you.



MINNESOTA  
MEDICAL  
ASSOCIATION



# News Briefs



## MMA ups its medical cannabis education efforts

The MMA has been busy preparing physicians and clinics for implementation of the state's new medical cannabis program. Since June 1, Minnesotans have been able to go to physicians to have their qualifying medical condition certified. On July 1, those who are certified and

successfully registered in the program will be able to obtain cannabis in either pill, liquid or oil form.

The MMA began its education efforts in late March with a forum in St. Paul, which was attended by more than 100 physicians either in person or online. It then published a 12-page special report on medical cannabis, which was distributed with the May issue of *Minnesota Medicine* and is available online at [www.mnmed.org/mc](http://www.mnmed.org/mc). In May, the MMA held two seminars/webinars for clinic administrators in Minneapolis and Edina. In addition, the MMA has produced a policies and procedure manual for Minnesota clinics that is now available for purchase. The manual can be customized by any clinic. For more information about the manual, visit [www.mnmed.org/mc](http://www.mnmed.org/mc).



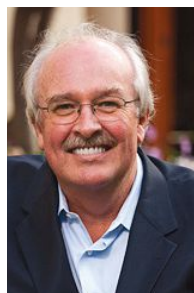
Patrick Zook, MD, and the MMA's Mandy Rubenstein

## St. Cloud doc receives national award

Patrick Zook, MD, was recognized as a Centers for Disease Control and Prevention (CDC) Childhood Immunization Champion for his work in the battle against

pertussis in the St. Cloud area. (In 2014, Zook organized a communitywide effort to increase immunization rates.) He received the award at a ceremony hosted by the Minnesota Department of Health in early May. Each year, the CDC and the CDC Foundation honor health professionals and community leaders from across the country who have gone above and beyond to promote or foster immunizations among children from birth to 2 years of

age. Zook, a long-time MMA member, is a family physician with St. Cloud Medical Group, where he has been caring for patients since 1977. He is also the current president of the Stearns Benton Medical Society.



Ian Morrison



Laurie Drill-Mellum, MD, MPH

## Speaker on physician well-being inked for Annual Conference

The MMA has signed another speaker for the 2015 Annual Conference. In addition to futurist Ian Mor-

rison, the September 25-26 event in St. Louis Park will feature Laurie Drill-Mellum, MD, MPH, who will present "Who Heals the Healer—Resiliency-Building Tips for Those Who Care for Others." Participants will learn to recognize the signs of burnout in clinicians, understand how it affects patient safety, identify practices and techniques that can reduce the effects of stress, and discuss physician wellness programs that promote healthy habits, resiliency and positive interactions. Annual Conference registration will open in July.



Musicians perform at the MMA's September 2013 Hippocrates Cafe at Mill City Clinic.

## Hippocrates Cafe coming to Annual Conference

Hippocrates Cafe, a live "show" that explores health and medicine through story and music, will be part of this year's Annual Conference. MMA member Jon Hallberg, MD, the creator and host of the show, will be accompanied by leading Twin Cities' actors who will interpret essays and poems written by Minnesota physicians and medical students and published in *Minnesota Medicine*. Musicians will perform before and after each piece. Physicians and medical students and their guests are invited to this free event that will take place the evening before the conference at the DoubleTree by Hilton in St. Louis Park.

PHOTO BY KATHRYN FORSS



Maya Babu, MD

### Member running unopposed for AMA board spot

MMA member Maya Babu, MD, a neurosurgery resident at Mayo Clinic, is running unopposed for a second two-year term as the Resident and Fellow Section member of the AMA Board of Trustees. She was first elected in June of 2013. Babu holds a BS in

neuroscience and a BA in psychology from the University of Minnesota. She also holds degrees from both Harvard Medical School and Harvard Business School.

### SGR finally fixed; now what?

After 17 annual short-term fixes, Congress finally voted on a permanent solution to the problematic Medicare Sustainable Growth Rate (SGR) formula in mid-April. Provisions in the new law increased the fee schedule conversion factor by 0.5 percent on July 1 and by another 0.5 percent on January 1, 2016. Also included is a new merit-based incentive payment system that will take effect January 2019. This new system will replace these other existing incentive programs on the last day of 2018: 1) the meaningful use incentive program for certified electronic health record technology, 2) the physician quality reporting incentive program, and 3) the value-based payment modifier. Details of the new system will be developed in the interim. The law also includes provisions for developing, evaluating and adopting alternative payment models, which could replace fee-for-service payments. The MMA is now examining what happens next for physicians who work with Medicare patients. Look to future issues of *Minnesota Medicine* and *MMA News Now* for details.

### New video series on pain, opioids and addiction now online

The MMA has made available five more videotaped sessions from its Pain, Opioids, and Addiction Lecture Series. CME credit is available for each. The lecture series is part of the MMA's efforts to fight prescription opioid misuse by educating medical students, residents and practicing physicians. It is made possible through

### On the calendar

Event	Date	Location
Preconference Hippocrates Cafe	Sept. 24	DoubleTree by Hilton, St. Louis Park
2015 Annual Conference	Sept. 25-26	DoubleTree by Hilton, St. Louis Park

Check the MMA's website ([www.mnmed.org/events](http://www.mnmed.org/events)) for more information and to register.

a partnership with the Steve Rummler Hope Foundation and the University of Minnesota Medical School. Find the videos at [www.mnmed.org/PainSeries](http://www.mnmed.org/PainSeries).



More than 100 people gathered for the networking event in Rochester.

### Rochester networking event draws large crowd

More than 100 physicians and physicians-in-training attended a free social event in Rochester on May 7. The MMA, Zumbro Valley Medical Society, and the MMA's Young Physicians, Resident and Fellow, and Medical Student sections hosted the event. Sponsors included the U.S. Air Force, Cambria, U.S. Army, Home Federal, U.S. Navy, Limb Lab, Clements Chevrolet, Cadillac, Subaru, and the MMA Foundation. The MMA plans to host similar events across the state.



Daniel Trajano, MD, (left) Susan Hoel, Stephen Eckrich, MD, and Sue Abderholden

### Physicians discuss physician-patient relationship at MMA conference

Physicians from across the state gathered in Bloomington in late April to explore the evolving relationship between physicians and patients. The day-long conference, convened by the MMA's Policy Council, included discussions about legal issues, end-of-life care, narrow provider networks, physician autonomy in making patient care policies and physician employment contracts. Throughout the day, attendees were polled about the importance of these and



other topics. The Policy Council will use the poll results to help craft future policy.

### Retired Minnesota physician receives humanitarian award

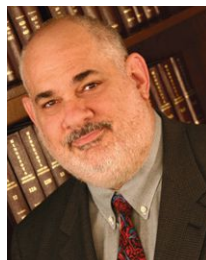
Helmut Diefenthal, MD, received the first-ever Humanitarian Award from the American College of Radiology in mid-May. For the past 30 years, Diefenthal and his wife, Ro, have lived and worked in Moshi, Tanzania. He formerly taught and practiced radiology at the University of Minnesota and Veterans Affairs Medical Center. He was profiled in the December 2009 issue of *Minnesota Medicine*. Diefenthal co-founded the East Africa Medical Assistance Foundation and helped create a sister organization called the Foundation for Cancer Care in Tanzania. **MM**

### Attention: Important Message for MMA Members

In mid-May, the MMA launched a new and improved membership database. It allows you to pay your dues and sign up for events online, and to better interact with the MMA. Your first encounter with the database will occur when you sign up for an MMA event or meeting. When you register for an event or meeting you will be prompted to enter an email address. If you **do not** have an email address in our system, you will be prompted to provide some general information before you can register. If you **do** have an email address in our system, you will see a screen that provides you the following option: "If you forgot or do not know your credentials, please click for email instructions." Click the link. You will then enter your email again and hit the reset password button. An email will be sent to you that will allow you to create a password that you should save and use in the future on the new membership database. If you have questions, please contact Jaime Olson (jolson@mnmed.org).



Donald Jacobs, MD



Robert Meiches, MD



Mandy Rubenstein



Cindy Firkins Smith



Doug Wood, MD



Janet Silversmith

## MMA in Action

MMA President **Donald Jacobs, MD**, met with the board of the Minnesota Dermatological Society in April at the University of Minnesota.

In mid-April, Jacobs, **Robert Meiches, MD**, MMA CEO, and **Mandy Rubenstein**, MMA manager of physician outreach, met with new CentraCare CEO **Kenneth Holmen, MD**.

MMA Trustee **Robert Koshnick, MD**, and Rubenstein met with physicians at Essentia Park Rapids for an MMA update and to discuss plans for the merging of several counties into the Clay Becker Medical Society.

MMA Immediate Past President **Cindy Firkins Smith, MD**, gave the keynote address to the University of Minnesota Medical Student Revisit Day. **Doug Wood, MD**, MMA board chair, also addressed the medical students.



**Dennis Kelly**, MMA Foundation CEO (middle), attended the Wisconsin Medical Society Foundation Gala in Madison in late April. He also presented on the Foundation's Physician Volunteerism Program at the Park Nicollet Senior Physicians Breakfast at Methodist Hospital in St. Louis Park.

In May, **Kelly, Jacobs, Juliana Milhofer**, MMA policy analyst, **Kim Kiser**, *Minnesota Medicine* editor, and **Dan Hauser**, MMA senior manager of media relations and communications, attended the Minnesota Department of Health's award ceremony for MMA member **Patrick Zook, MD**, recipient of the CDC Childhood Immunization Champion (see story on page 26).

In April, **Dave Renner**, MMA director of state and federal legislation, presented a legislative update at the Mankato Clinic Annual Board Retreat.

**Janet Silversmith**, MMA director of health policy, gave a general MMA and legislative update to Affiliated Community Medical Centers' board in Alexandria in April.

**Brian Strub** and **Kathleen Baumbach**, MMA managers of physician outreach, attended the Minnesota Chapter of the American Academy of Pediatrics conference in Bloomington in early May.



## VIEWPOINT

# We need a stronger voice

I've been looking back at the 2015 legislative session and reviewing what the MMA accomplished and failed to accomplish at the Capital this year. This got me thinking about what we were able to do with our limited resources, and about what else we could have done for Minnesota physicians if we had more members.

Our goals are clear and, quite frankly, shared by many stakeholders in the health care system: We want to make Minnesotans the healthiest in the nation and offer health care at a price they can afford. Critical to that is ensuring the viability of medical practice in the state for all physicians, whether they're solo practitioners, members of small groups or employed by a large system. We need your help to make that happen.

Because you are reading this, you are likely an MMA member. Thank you for your support. Many of your colleagues, however, are not. And I would like your help in changing that. The reason is straightforward—our voice in the debates over health care is critical and it's currently too weak. We have neither the engagement nor the financial resources to effectively take on some of the strong forces, the pockets of self-interest and misguided policy that are eroding physician practice.

This year, we started to address oppressive administrative burden through an effort to significantly overhaul a badly flawed and costly medication prior authorization process. We were up against the health plans and other payers and didn't prevail. The House listened to the health plans' argument that the bill we backed would significantly hamper their ability to control costs. Would more representatives and senators have been convinced by our

arguments—that it impedes care and adds to cost—if more physicians had stepped up to testify? We will continue this work, but we need your help if we are to win this battle and if we are to identify the next targets for meaningful reform.

Given the importance of protecting and enhancing physician practice, the cost of membership in the MMA and component medical societies is low (less than 0.5 percent of the average Minnesota physician's income). We could do so much more if everyone became a member. Other professionals join their associations. In Minnesota, for example, 76 percent of dentists belong to the state dental association. As physicians, we fall well short of that measure. (About 35 percent of Minnesota's physicians are members of the MMA.)

The MMA is changing structurally and strategically to better take on the challenges affecting all physicians in our state. And the MMA is striving to change working conditions for physicians in the state. Change is hard. It rarely occurs without great effort, and is almost never accomplished without a cost. We need you, and we need your colleagues to join with us as we seek to ensure the future of medical practice in the state. Reach out to fellow physicians and tell them why you are member and why we are stronger together. Let them know that as a member, their voice will be heard and will make a difference.

With more members, our voice will become stronger as we take on issues of concern to all. **MM**



Donald Jacobs, MD

We need you, and we need your colleagues to join with us as we seek to ensure the future of medical practice in the state.

# Smartphones and security

Safeguarding the information in your pocket

BY TRISH LUGTU

The federal Office for Civil Rights (OCR) decided to make an example of a 12-bed hospice in Idaho after an unencrypted laptop was stolen from an employee's car in June of 2010. The laptop contained information about 441 patients. Investigators found the hospice had not properly safeguarded electronic protected health information (PHI), nor did it have in place policies or procedures to address mobile device security. The case ended with a \$50,000 settlement.<sup>1</sup> OCR Director Leon Rodriguez, was quoted as saying, "This action sends a strong message to the health care industry that, regardless of size, covered entities must take action and will be held accountable for safeguarding their patients' health information."

Theft of PHI is a growing concern among health care organizations. It currently accounts for 53 percent of HIPAA violations.<sup>2</sup> Loss accounts for 18 percent. Mobile devices are of particular concern because they can easily be lost or stolen.

Theft of devices is just one aspect of a bigger issue: how to keep patient information safe in the era of wireless networks and mobile devices. Currently, more than 80 percent of physicians use smartphones, and increasingly they are using their phones and other mobile devices (laptops and tablets) to access patient records and other features within their organization's electronic health record (EHR) systems.<sup>3</sup> With health information technology systems now encompassing not only wired workstations but also wireless networks and with the development of new devices and apps, organizations need to examine



their security systems and policies. And physicians themselves need to consider how they're using even their personal devices in the course of the day.

## How physicians use smartphones and mobile devices

James Avallone of Manhattan Research says physicians tend to use smartphones for "short burst" activities such as checking schedules, communicating with care team members and having instant access to drug reference databases.<sup>3</sup> They use devices with larger screens such as tablets or laptops for doing "longform type research," accessing their EHRs and pursuing continuing medical education.<sup>3</sup>

Another recent study identified five categories of physician mobile device use—administration, health record maintenance and access, communications and consulting, reference and information gathering, and medical education. Searching and managing their schedules were their leading activities.<sup>4</sup>

Also important to note is that physicians tend to use smartphones, tablets and laptops in conjunction with, rather than in lieu of, one another, and that they often use their own devices. One survey by WPP's Kantar Media done in March of 2013 found that three-quarters of physicians use their personal smartphones at work.<sup>5</sup> This may complicate how they perceive who governs their phones and the information they contain. Although it may be in a physician's best interest to secure and protect mobile devices and the personal information they contain,

the laws don't govern what each person may do with his or her personal information. However, when PHI pertaining to a patient is involved, the physician is legally obligated to secure and protect it and any mobile device through which it can be accessed in accordance with the Minnesota Health Records Act and the federal HIPAA law.

Understanding which apps and devices physicians use, the type of information kept in each app, and how information flows between devices is critical to identifying where security might break down.

## Where the vulnerabilities lie

### *Devices*

Regardless of whether they own the device or their employer does, physicians need to understand that they are legally obligated to protect the device if they use it to access patient-related PHI. In the case of the Idaho hospice, encryption would have made the stolen information unusable, unreadable and undecipherable. (If a mobile device containing encrypted PHI is stolen, it is not considered a HIPAA breach.)

### *Emails, texts and calendars*

If you access patient health records on your mobile device, then you need to safeguard that device. And the obligation doesn't end with patients' medical records. Emails and text messages that contain PHI are also vulnerable (many organizations have policies that prohibit disclosure of PHI in email or text messages). Administrative activities such as time tracking, time management and scheduling may

seem benign. However, if details about patient PHI are kept in tracking or calendar apps, further assessment is warranted.

#### *The cloud*

Physicians often think that information stored in the cloud and not on their devices is safe. That's not necessarily true. Cloud users should consider the following: Does the app save your user ID and password for seamless sign on? If so, does the screen of your phone or tablet lock when it's not in use? Is the data that is being transmitted encrypted and is the data at rest (stored in memory) encrypted? Vendors can't control how each person handles his or her smartphone, rendering it impossible for them to remove all security threats that might affect it.

Here's a quick-and-easy test you can use to check for potential vulnerability. If you put your phone in airplane mode, what PHI can you see in apps, photos, messages and emails? If you can see PHI on your phone in airplane mode, then it is not just "in the cloud."

#### *Native apps*

Maybe the secure cloud-based app is truly secure. Unfortunately, it isn't the only app on your smartphone. Do you email, text message, take photos, use voice memos or notes? Those are apps, too. Many of them come already installed on your phone or tablet, and many of them are vulnerable.

#### *Synchronization of devices*

You may be disclosing PHI within communications such as emails or text messages if your phone is synchronizing emails sent from your laptop (the information may also be housed on your email server). In other words, even if you don't send PHI in emails from your phone, you might still be exposing PHI if your phone is synched with your laptop or desktop computer. If you're not sure if it is, try searching on your phone for an email with known PHI that you sent from your laptop or workstation.

## How to protect patient information

Whether you use your own mobile device or one provided by your employer, you should understand how to protect health information. The following tips can help you secure such information:

- Install and enable encryption software to protect health information stored or sent by mobile devices
- Use a password or other user authentication
- Install and activate wiping and/or remote disabling to erase the data on your mobile device if it is lost or stolen
- Disable or do not install or use file-sharing applications
- Install and enable a firewall to block unauthorized access
- Install and enable security software to protect against malicious applications, viruses, spyware and malware-based attacks
- Keep your security software up to date
- Research mobile applications before downloading them
- Maintain physical control of your mobile device. Know where it is at all times to limit the risk of unauthorized use
- Use adequate security to send or receive health information over public Wi-Fi networks
- Delete all stored health information on your mobile device before discarding it.

Source: Mobile Device Privacy and Security. Available at: [www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device](http://www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device).

#### *Photos*

Photos also need to be considered. More and more physicians are taking photos—of an affected area or of films or scans—to send (sometimes by text) to colleagues for informal consults or educational purposes. The vulnerability in this case results when the texts and photos are not managed or deleted.

#### *Back ups*

Copies of the PHI on your smartphone also can be replicated to the cloud, laptops and other external backups. If you back up your device in the cloud, how secure is the system you are using? If you back up your smartphone on your laptop, how secure is your laptop and who else has access to it? If you're backing up your laptop to another external drive, how secure is that?

## Conclusion

The first step in protecting patient information is awareness. Assess how you use your smartphone and other devices and look for ways PHI may be placed on them without your knowledge. Know where copies of data may be replicated in backups. Finally, safeguard your devices as appropriate.

Mobile devices are likely to become even more integrated into medical practice. It's imperative that you and others in your organization understand the risks of using them to access and transmit PHI and take measures to safeguard such information. **MM**

Trish Lugtu is associate director of research at MMIC.

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# The new world of genomic testing, families and privacy

Can physicians and researchers share information with family members who may be at risk for heritable diseases?

BY SUSAN M. WOLF, JD

As genomic testing—including genome and exome sequencing—becomes more established and affordable, an increasing number of physicians are encountering genomics in their practice. Sequencing of cancer patients and their tumors is becoming an accepted part of oncology practice. Sequencing is used in other specialties as well, for example to aid in the diagnosis of pediatric patients with puzzling neurodevelopmental anomalies. As an increasing number of patients undergo genomic analysis, physicians will face challenging privacy issues.

Like other medical information, genetic data is typically regarded as private, and physicians have stringent responsibilities to protect it, as a matter of law, ethics and institutional policy. But families are beginning to come forward and ask whether genomic information about an individual family member may have implications for their own health. This may present physicians with a new version of an old dilemma: Do they protect the privacy of the

patient’s genomic information, or do they share that information with relatives?

This problem first surfaced with the rise of traditional genetic testing. Genomic analysis can yield much more information revealing multiple genetic risks. Some of those risks are serious and some may be lowered or even eliminated through clinical intervention. This means that information about genetic variants may be highly important to relatives, especially since first-degree biological relatives commonly share 50 percent of their genes.

Here’s a possible scenario: A physician learns that her patient has a *BRCA1* gene mutation, conferring increased risk for breast and ovarian cancer. In the course of a consultation, the doctor recommends that the patient share this information with close relatives, so they can consider being tested. The patient replies that she’s not willing to disclose the mutation because she’s estranged from her family. What is the doctor to do? Do family members have a right to know?

## The physician’s role

In the 1990s, lawsuits were filed claiming that physicians had a “duty to warn” patients and relatives about hereditary disease risk. The case law that emerged from those suits was inconsistent. The Supreme Court of Florida ruled in 1995 that it was enough for the physician to warn a patient that a disease is heritable, leaving the responsibility with the patient to share that information with family members. However, in a 1996 case from New Jersey, the court found a broader responsibility to warn at-risk relatives. The court required that “reasonable steps be taken to assure that the information reaches those likely to be affected.”<sup>1,2</sup>

These cases unleashed a flurry of commentary. Overwhelmingly, legal and policy authorities urged the importance of continuing to respect the confidentiality of patient information. In 1996, the Health Insurance Portability and Accountability Act (HIPAA) was passed. HIPAA protects the privacy of health information for 50 years after an individual’s death. That protection applies to patients’ genetic and genomic information as well.

In 1998, the American Society of Human Genetics (ASHG) released guidelines for health care professionals, in which they recognized that genetic information is “personal—yet simultaneously familial” and “raises new and profound questions about ... legal and moral obligations to disclose genetic information to at-risk relatives.” The guidelines specifically focused on what doctors should do if a patient refuses to disclose relevant genetic information to at-risk relatives. The ASHG asserted that:

- Patient confidentiality should be paramount and a breach of confidentiality should be highly exceptional.
- Confidentiality is not absolute: “ethical, legal, and statutory obligations may ... permit physicians to disclose otherwise confidential information.”

Under these guidelines, doctors must stay within a narrow zone. They have the privilege to warn, but only in cases “where attempts to encourage disclosure on the

part of the patient have failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk.”<sup>3</sup> The ASHG thus recognized a privilege to warn in these narrow circumstances, not a duty to warn.

In the case of the patient refusing to share information about a *BRCA1* mutation with family members, the physician would be on firmer ground encouraging the patient to reconsider her refusal, rather than reaching out directly to family members.

### No established guidance available to researchers

All of this means clinicians have some guidance regarding what genomic data they can disclose and to whom. The same cannot be said for researchers, who collect data to address broad scientific questions, rather than to determine a course of treatment for one patient. Only now are policies emerging to guide researchers and biobanks about what to do with individual research results as well as unexpected “incidental findings”—discoveries that researchers may stumble upon in performing their primary analysis and consider offering to the research participant because of the potential health importance for that individual.<sup>4,5</sup>

Adding to the challenge is the fact that these same issues may arise after the death of the research participant. Genomic research commonly involves archiving data and specimens for long periods of time to facilitate continued research. Especially in the case of cancer, the individual whose genome was sequenced may die, leaving relatives concerned about their own risk.

Let’s say a cancer researcher finds that a subject who died carried a genomic variant placing him at higher risk of colorectal cancer or a variant for malignant hyperthermia that indicated a potentially catastrophic reaction to a commonly used anesthetic. What should the researcher do

with this information? The researcher may have no relationship with surviving family members and may not even be a clinician. In any case, the researcher likely promised to protect the confidentiality of the subject’s health information when obtaining informed consent for participation in the research.

### Moving forward

When the debate over the duty or privilege to warn family members of potential genetic risk first began, the human genome had not yet been sequenced. Now that sequencing and other forms of genomic testing are readily available—both in research and increasingly in clinical care—we can-

## The consortium’s contributions

Since 2005, the University of Minnesota’s Consortium on Law and Values in Health, Environment and the Life Sciences has collaborated with scholars across the country on a series of National Institutes of Health (NIH)-funded projects analyzing the issues involved in the return of genomic results and incidental findings to research participants. The resulting publications have had a major impact on the national debate.

When the consortium first started working on these issues, there was little discussion about how to handle findings that might be important to individual research participants when conducting genomic research. Researchers analyzing scans using MRI and other technologies had already recognized that incidental findings were inevitable in research and had begun to devise consensus guidelines for grading the urgency of such findings and managing them. Consortium work built on that early foundation to create guidance for genetic and genomic findings, which was published in a dedicated issue of the *Journal of Law, Medicine & Ethics* in 2008.

Our next project funded by the NIH grappled with the reality that genomic data and specimens are often archived in biobanks and large, shared databases for long-term research use all over the world. This raises the potential for research results and incidental findings to be uncovered at the biobank or data archive or in subsequent research by teams that may be far removed from the source individual. That work resulted in a special issue of *Genetics in Medicine* in 2012.

Our latest NIH research, with colleagues at the Mayo Clinic and the University of California, San Francisco, addresses return of results and incidental findings to family members, including after the death of the research participant. As part of that project, we co-directed a workshop on return of results from biobanks at the Brocher Foundation in Switzerland in November 2013.

NIH Director Francis Collins has declared the issue of incidental findings “one of the thorniest current challenges in clinical research.”<sup>1</sup> In 2013, the Presidential Commission for the Study of Bioethical Issues devoted an entire report to the problem.<sup>2</sup> The NIH now dedicates substantial funding to these issues and has formed the Clinical Sequencing Exploratory Research (CSER) Consortium to speed progress.<sup>3</sup> The University of Minnesota’s Consortium participates actively in CSER work and collaborates with scholars all over the world on these high-impact issues.

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not ignore the tension between protecting individual privacy and facing the reality of shared risk in biological relatives. U.S. privacy law is about protecting individuals, but genetics is about more than individuals; is it about kin.

Efforts are under way to craft policy sensitive to these new realities. At the University of Minnesota's Consortium on Law and Values in Health, Environment and the Life Sciences, we are engaged in a multi-year project funded by the National Institutes of Health to study these issues and create new guidelines (see p. 33).<sup>6</sup> In partnership with researchers at the Mayo Clinic and the University of California, San Francisco, we have convened a multidisciplinary group of experts from the United States and Canada to draft consensus recommendations on the return of results to family members, both before and after the research participant's death. Those recommendations will be published in the fall in a symposium issue of the *Journal of Law, Medicine & Ethics*, which will feature 15 articles stemming from our national conference on families and genomic privacy last November.

Central to the project recommendations is the need to face this issue and plan for it. Researchers inviting individuals to participate in genomic research need to be clear on the privacy protections for the individual's genomic data both before and after their death. Researchers can ask prospective participants whether they wish to have data shared with family members and who they trust to make decisions about information-sharing after they can no longer make those decisions themselves. Clinicians, too, can broach these issues with patients. Both can seek counsel on the complex questions of family access under state and federal law.

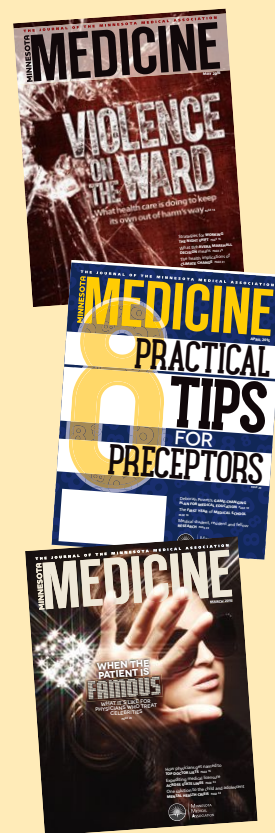
As genomics increasingly becomes part of the practice of medicine, these issues will become more and more important. Families, researchers and clinicians need to start talking about who will get access to genomic results, including after an individual dies. We plan who gets our property after death. We need to start planning who will have access to our genomic data. **MM**

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# The Minnesota Health Records Act and HIPAA

In Minnesota, physicians must abide by two laws governing the sharing of health information—and that's creating some difficulties.

BY TERESA KNOEDLER, JD

Most physicians and patients are familiar with Health Insurance Portability and Accountability Act (HIPAA), the federal law that governs the privacy of health information. What many don't know is that HIPAA is not the only law that applies to health information in Minnesota. The Minnesota Health Records Act (MHRA) also places limits on when and how private health information may be disclosed. Minnesota clinics and hospitals must comply with both the federal and state laws regarding health data privacy. Increasingly, clinicians and patients are discovering that having parallel laws is not helpful and that in some cases the differences between them can hinder the quality of patient care.

## The state law

The MRHA is described in Minn. Stat. § 144.291-144.34. It was passed in the 1980s, as an effort to ensure health privacy in the absence of federal regulation. The MHRA was largely championed by a very small-but-vocal group of privacy advocates. Its most salient component is the section that states that protected health information may only be disclosed by a health care provider with express consent from the patient for the specific disclosure. In other words, the patient must give their physician consent to speak to each of their other health care providers. This law applies to all situations in which disclosure may be



necessary, including treatment coordination and payment.

The MHRA addresses only the disclosure of protected health information. It does not address who has access to the information or how it can be used. Nor does it include provisions about electronic data security, monitoring access to electronic data or data breach notification procedures. In addition, the MHRA has no mechanism for update or oversight.

There are a few exceptions to MHRA's broad requirement that no health information be disclosed without specific consent. One permits a clinician within an organization or private practice group to share a patient's health information with members

of that group, so long as doing so is salient to the treatment of that patient. There is also an exception for medical emergencies when the patient is unable to give consent.

Minnesota and New York are the only states that maintain separate health records privacy statutes. All other states adhere only to HIPAA's standard, which specifies that health information may be exchanged between providers for the purposes of treatment without specific consent from the patient.

A health care provider who violates the MHRA is subject to licensure actions. In addition, the provider is liable to the patient directly in the case of a violation.

**The federal law**

HIPAA was originally enacted in 1996 and has evolved significantly since then. It very broadly set out to establish national standards for the management of electronic health care and transactions data. However, as privacy concerns associated with electronic data exchange became clear, additional privacy and security requirements were added in 2000. Those provisions were designed to balance the need to protect patient privacy against the need for timely sharing of relevant health information.

Generally, HIPAA permits the use and disclosure of protected health information for treatment, payment and health care operations including quality assessment, auditing and underwriting; managing provider licensure and performance; and business planning and development. For example, HIPAA permits the sharing of information among providers for the purpose of coordinating treatment without the patient’s consent. Information also can be shared without patient consent among providers and certain nonproviders who fulfill health care operations such as off-site IT storage.

HIPAA applies only to covered entities, which most commonly include all health care providers and health insurers. The law also applies to contractors who carry out certain functions on behalf of those entities, for example the IT vendor who maintains a small clinic’s EHR or the billing agency that collects overdue bills from patients on behalf of a large hospital system; these are known as business associates. Although these contractors do not provide health care, they must safeguard protected health information as if they were health care providers.

HIPAA also generally requires that covered entities or their business associates only use or disclose the “minimum necessary” amount of protected health information required to accomplish the goal they are trying to achieve. This means that even if someone has the right under the law to access another person’s health records, their right to access them may be very

limited, depending on what they need to accomplish.

All entities covered under HIPAA are required to build compliance into their business model through policies and procedures, provide training to all who access protected health information, appoint a designated privacy officer, and engage in extensive internal monitoring and auditing. Government oversight of HIPAA compliance is extensive, and the federal government has the power to pursue both civil and criminal penalties for HIPAA violations.

**Why two rules?**

The MHRA was passed long before HIPAA became law. Its goal was to ensure some degree of privacy of health data in the absence of any other state or federal statute addressing health data privacy at the time. HIPAA permits states to have laws on health information so long as they are not contradictory; because the MHRA is more stringent than HIPAA regarding the disclosure of protected health information, the two may coexist and concurrently apply to disclosure of private health information in Minnesota.

The MHRA is fairly straightforward and narrow. Its intent is to limit the disclosure of health information. HIPAA is much more broad and is intended to be a comprehensive regulatory scheme for the disclosure, use, management, transfer and security of health information. In that sense, if the MHRA were overlaid onto HIPAA, only a tiny piece would overlap.

**The problem with parallel laws**

These parallel regulatory structures create two types of problems. First, they increase the administrative load for clinics, hospitals and other covered entities, all of which must comply with two distinct and different statutory schemes to address disclosure of private health information. Second, the additional barriers imposed by the MHRA may lead to breakdowns in patient care coordination.

HIPAA permits clinicians who are coordinating treatment for a patient to share that patient’s health information. The

MHRA does not permit that. Nor does it generally allow for the use of “global” consent forms that would allow a patient’s primary care physician to speak to the specialist physicians or other providers caring for that patient about his or her condition. Instead, the MHRA requires that for each instance in which clinicians wish to communicate with each other about a patient (even a telephone call that might involve discussion of protected health information), the patient must sign a specific consent form, authorizing each provider to speak to the others. Further, the MHRA requires that consent be obtained each year. Thus, the cost associated with complying with both HIPAA and the MHRA is high.

Most of the meaningful protections we commonly associate with the security and privacy of our health information arise from HIPAA, not from the MHRA. HIPAA is what prevents a clerical employee in a large health system from perusing patients’ electronic health records for entertainment. HIPAA is what mandates that a document retention vendor maintain patient privacy as if that vendor were himself a health care provider. In contrast, the MHRA poses a significant barrier to timely and coordinated patient care and has little meaningful enforcement.

There is a broad coalition of physicians, clinics, hospital systems and health insurers that wish to reconcile the two laws. The need for cohesive health information policy and law is growing because of the imperative for sharing accountability for care that has come with the Affordable Care Act. It is not possible to consistently deliver quality, cost-effective care without first possessing all relevant health data. The MHRA prevents this from happening. **MM**

Teresa Knoedler is the MMA’s policy counsel.

# The Pilot-Patient and Mental Health

BY DANIEL DANCZYK, MD, STEVEN I. ALTCHULER, PHD, MD, AND LAWRENCE STEINKRAUS, MD, MPH

The recent crash of an airliner in the French Alps drew attention to the critical importance of the mental health of pilots and the key role physicians play in determining whether a pilot is fit to fly. This article reviews Federal Aviation Administration regulations and guidelines for making that determination and discusses the role of both the aviation medical examiner and the community physician in caring for pilots. It also offers community physicians tips for building solid relationships with pilot-patients so as to ensure they receive the best care possible.

In the wake of the Germanwings airline crash in the French Alps that killed 150 people last March, many airline passengers now wonder as they board their flight: What are the chances that the pilot has a mental health condition? Physicians likely have a different concern: What if my patient is a pilot?<sup>1</sup> The Germanwings crash is particularly disturbing to physicians because it involved a pilot who apparently had been treated for a mental illness. At least one clinician had not considered him capable of working just days or weeks prior to the crash, suggesting he was not “fit to fly.” Yet, of course, he did.

The crash is one of six international passenger air disasters likely involving pilot suicide/homicide that have occurred since 1956.<sup>2-5</sup> A National Transportation Safety Board study found eight confirmed aircraft-assisted suicides in the United States involving private and recreational flights between 2003 and 2012.<sup>6</sup> That study’s authors noted that this was half the number reported between 1993 and 2002. Yet they, along with Vuorio et al, have

suggested that the frequency of aircraft-assisted suicide is likely underestimated.<sup>5,6</sup> Still, such events, while tragic, are rare.

Depression and anxiety, however, are not, and these common conditions affect pilots as they do the general population.<sup>7-11</sup> At the very least, pilots are not immune to them.<sup>10-13</sup> The number of claims for disability caused by mental/nervous conditions has risen since 9/11, and mental/nervous disorders are now among the top five reasons claims are filed.<sup>13</sup>

The recent disaster highlights the concern that pilots with mental-health disorders may be under-treated or not treated at all.<sup>5,13</sup> One reason for this is the continued stigma around mental health diagnoses, which often drives pilots to mask their illness when seeing an aviation medical examiner (AME). An AME is a physician who has received Federal Aviation Administration (FAA) training to medically certify pilots by providing initial and recurrent fitness-for-duty evaluations. Pilots who transport passengers must undergo such an exam every six months if they are older than 40 years of age; otherwise, they are required to have one annually. Pilots

know that if they are diagnosed with a mental illness or another health problem their medical certification may be threatened, thus putting their job in jeopardy. Pilots also know of colleagues who have lost their jobs, portions of their retirement or hard-won seniority in recent airline bankruptcies and mergers. Thus, whether consciously or subconsciously, they often are motivated to appear “content and healthy” during a medical certification exam,<sup>6</sup> a phenomenon called “reverse malingering” or “faking good.”<sup>14</sup>

## Determining “Fitness to Fly”

The AME makes the initial determination about whether a pilot is fit to fly at the point of care. During the flight physical, he or she goes through a formal questionnaire (FAA Form 8500-8),<sup>15</sup> takes a medical history and performs a physical exam. The mental health element of the exam consists of the questions on the form, the review by the AME and a global mental status assessment during the physical. Formal psychiatric examination is not mandatory unless indicated by history or exam. If there are



no potentially disqualifying diagnoses, the AME may issue the pilot a medical certificate. If there are potential disqualifying diagnoses, then the AME must temporarily disqualify (“ground”) the pilot and defer the final fitness-to-fly determination to the FAA pending additional workup.

Although it might seem the mere presence of any psychiatric illness would disqualify a pilot from flying, that is not the case. Federal aviation regulations (FARs) do not mention depression and anxiety specifically as disqualifying conditions. Instead, the regulations state that a pilot with any mental health condition that makes him or her unable to perform their duties or unable to do so safely is disqualified.<sup>14,15</sup> Conditions that lead to cognitive impairment are particularly troublesome, as they can lead to poor decision-making and slower response times.<sup>15,16</sup> Certain things, however, are disqualifying. These include bipolar disorder, psychosis, attention deficit hyperactivity disorder, personality disorder, substance abuse and dependence, neurosis and a suicide attempt.<sup>15,17</sup>

The FAA expects pilots to self-regulate between flight physicals, and the culture of assessing and reassessing one’s abilities is ingrained in them during their training.<sup>14</sup> The question “Am I fit for duty and fit to fly?” is on the various risk-mitigation checklists that pilots are trained to and expected to use.<sup>15</sup>

Research has helped illuminate that determining whether a pilot is fit to fly is nuanced. Jones noted that almost half of Air Force fliers grounded for psychiatric reasons were later able to resume unrestricted flying duties.<sup>4</sup> Eleven out of 14 Air Force aircrew members (pilots and nonpilots) who had attempted suicide were later able to return to flying duties.<sup>18</sup> Rayman states that the concern is “... whether the pilot’s emotional state is likely to interfere with [his or her] duties.”<sup>16</sup> Jones and Marsh

noted that pilots may have symptoms that do not rise to the level of a clinical disorder but may still interfere with flight safety.<sup>14</sup>

The FAA and other aviation regulatory groups provide options for pilots who have a history of mental health disorders and wish to continue flying. These are available to both commercial pilots and those who fly recreationally. Depending on the pilot’s diagnostic history, an AME may issue a certificate provided strict criteria are met.<sup>17</sup> For example, the AME may certify a pilot who was diagnosed with adjustment disorder or minor depression and treated with medication for fewer than six months if the condition has stabilized or resolved, and if there is no recurrent episode history and the medication was discontinued for at least three months. If the AME must ground a pilot, the pilot may elect to pursue a waiver (“special issuance”) in order to fly again. Through this program, the FAA has the authority to allow pilots with disqualifying conditions to return to flight duties. A special issuance certification usually comes with conditions for monitoring and recurrent testing based on the condition.

Civilian pilots in the United States initiate the process of seeking a special issuance certification through their AME. To apply, pilots with a mental health concern must first undergo a rigorous evaluation by aviation-knowledgeable psychiatrists and neuropsychologists. Their final evaluations and the results of the AME’s examination are then reviewed by an FAA expert panel.<sup>14</sup>

### The Role of the Community Physician

Clinicians who get to know the pilots they care for will be in the best position to accurately determine whether they are fit to fly. Commercial pilots see their AMEs once every six to 12 months. In reality, given the high turnover within aviation companies and their changing locations, pilots often are not able to establish a long-term relationship with one AME. Moreover, even if there is an established relationship between an AME and pilot,

the nature of the aviation medical exam is regulatory.

Ideally, the pilot would bring his or her medical concerns to the AME during an exam, and the AME would educate the pilot about how the FAA views certain treatment protocols vis-à-vis obtaining a special issuance certification. The pilot would then take this information back to his or her treating physician. But during their FAA exams, pilots may be reluctant to bring up medical concerns because of fears about being grounded. Any medical condition that might result in a greater than 1% likelihood of sudden in-flight incapacitation (eg, coronary heart disease and diabetes) would disqualify a pilot from flying.<sup>19</sup> Because of this, the community physician may be in the best place to engage pilots as patients.<sup>6</sup> And as such, they may be in the best position to assess their competency.

Of course, all of the same things that apply to establishing a relationship with any patient apply to establishing a relationship with a pilot. You need to engage them and get to know them as individuals. In addition, you also should seek to understand, from their perspective, the professional and personal demands they face. Ask them about their ability to control these things. For pilots, who are used to being in control, the inability to control something is tantamount to getting “behind the plane” or potentially losing control of the aircraft (and at the very least not knowing momentarily what the plane is or should be doing). Learning about these things may give you a window into their psyche and their coping mechanisms. The hope is that once you have established a relationship, the pilot-patient will tell you what you need to know.

If your pilot-patient appears reluctant to answer your questions about their mental/emotional well-being, be transparent. Ask about their hesitance. Remind them that you are there to provide confidential advice and that you will respect both their privacy and their responsibility as a “pilot-

in-command.” Use that term and you will immediately catch their attention because they will know that you have some understanding of the aeronautical decision-making that comes with staying “ahead of the plane” (initiating or changing actions ahead of time to ensure the plane does what the pilot wants it to do).

If the pilot-patient is concerned about medical disqualification, validate that. Remind the pilot it is their responsibility, not yours, to tell the AME about the medical problem. Inform him or her that you are willing to assist in every way possible to help him or her maintain their flying status or get it back and that part of that assistance is treatment. Explain that treatment for a mental illness may include counseling, taking medication or a combination of the two. Moreover, remind the pilot that treatment also may include the recommendation to not fly for a period, giving them permission to take time off from work. The FAA instructs pilots to not fly until they are “satisfactorily recovered” from an emotionally upsetting event such as a serious argument, death in the family, separation/divorce, job loss or financial ruin.<sup>15</sup>

Educating the pilot-patient is the best thing you can do. Let your patient know that the more he or she resists a possible solution to the problem, the greater the likelihood that it could turn into one that is irreparable from an aeromedical perspective. Pilots understand the concept of preventive maintenance, so use it and encourage them to invest in maintaining their ability to fly.

One last bit of advice: If you find yourself in a difficult position, get a curbside consult from an FAA medical representative or flight surgeon. You can find their contact information on the FAA website<sup>20</sup> or by Googling “FAA regional flight surgeons.” You may find the flight surgeon’s answers to your questions helpful. And they might offer insight into how you should approach a particular pilot-patient.

If you have a safety concern or an uncomfortable gut feeling about a pilot-patient, you may call the FAA and leave a detailed anonymous message.

## Conclusion

Although the Germanwings disaster was tragic, it has helped raise awareness about the importance of pilot health, including mental health. Treating pilot-patients can be very rewarding because nearly all of them are highly motivated to stay or become healthy. The best approach to working with them is to establish an alliance with them. Once you have gained their trust, most pilots will come to you when they have a health concern.

All physicians have the skills and experience to deal with the clinical issues affecting pilot-patients. If they have a long-term relationship with a pilot, they will be better able to intervene early, allowing any illness including a mental illness to be detected and treated before it worsens. Physicians who treat pilots need to be mindful that their efforts are critical to maintaining not only the pilot-patient’s health but also public safety. **MM**

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# Insights from a Review of Medical Cannabis Clinical Trials

BY TOM ARNESON, MD, MPH

The Minnesota Legislature passed a law establishing a medical cannabis program in 2014. One of the first tasks of staff in the new Office of Medical Cannabis at the Minnesota Department of Health was to review scientific literature on medical cannabis. The review was limited to studies involving products similar to those allowed in Minnesota. This article explains how the review was conducted and presents three themes that emerged from it.

In May of 2014, the Minnesota Legislature passed and the governor signed a law establishing the state's medical cannabis program. Since then, patients, health care professionals and provider organizations, the two companies that will produce and distribute medical cannabis products, the Minnesota Department of Health, law enforcement professionals and others have been preparing for its implementation. Enrollment of patients began June 1, and distribution of medical cannabis products will start July 1. This article describes and discusses one aspect of that preparation: a review of relevant medical literature that was conducted by staff from the Minnesota Department of Health's Office of Medical Cannabis (OMC).

The purpose of the review, which was required by statute, was to inform selection of the formulations and dosages of medical cannabis that would be available through the program. The only medical cannabis products allowed in Minnesota are liquids or oils produced by an extraction process involving use of high-pressure liquid carbon dioxide. The liquid or oil will contain hundreds of the chemicals present in the cannabis plant. The exact

composition of the liquids and oils will depend on the strain of the plant, how it was grown and the specifics of the extraction process.

One category of chemicals that will be found in the extract is a group of 21 carbon terpenoids distinctive to plants of the cannabis genus called cannabinoids. The two most abundant and best-studied cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is psychoactive and produces the "high" well known to recreational marijuana users. CBD does not produce that high. In fact, it appears CBD attenuates the high produced by THC. Scores of additional cannabinoids are present in small amounts in the extract; most have not been fully studied. For the literature review, studies of cannabis extraction products and synthetic THC or dronabinol, which the FDA approved for certain con-

ditions in 1985 and is sold under the brand name Marinol, were deemed relevant.

A report on the findings of the literature review was published in December 2014. It includes summaries of clinical trials and prospective observational studies in humans published in peer-reviewed journals that focused on medical cannabis formulations consistent with those that will be used in Minnesota's program.

## The Review

To conduct the review, we searched the National Library of Medicine's MEDLINE database using key words appropriate for each qualifying medical condition. Articles that appeared to report results of clinical trials or reviews of clinical trials were examined. References in those articles were studied to identify additional articles. We continued in an iterative fashion until no additional relevant articles were found. Finally, we searched the [clinicaltrials.gov](http://clinicaltrials.gov) website for medical cannabis trials that were under way or under development and for additional articles on completed trials.

We identified 50 studies for inclusion in our review. In addition, we included a systematic review and meta-analysis of 30 studies dealing with cancer-associated

## Read the full report

"A Review of Medical Cannabis Studies Relating to Chemical Compositions and Dosages for Qualifying Medical Conditions" is available at: [www.health.state.mn.us/topics/cannabis/practitioners/dosage.pdf](http://www.health.state.mn.us/topics/cannabis/practitioners/dosage.pdf).



nausea and vomiting. We read each article and extracted key information on study design and size, agent and dosage, effectiveness outcomes, and side effect outcomes.

It should be noted that the studies were not evenly distributed across medical conditions. For example, we found 17 different studies on use of medical cannabis for treating muscle spasm but fewer than three each for glaucoma, Tourette’s syndrome, ALS and Crohn’s disease. Although additional studies involving smoked cannabis were found, they were not included in our review because Minnesota does not allow the use of smoked cannabis. For each of the nine conditions for which medical cannabis use is approved in Minnesota, the report provides an overview of the studies and a summary of each specific study (Table).

In this article, I share some observations I’ve made after reading the literature. These are general comments rather than recommendations about specific products, doses and conditions.

**Observations**

*Mild and moderate side effects are common, but very few serious adverse events related to cannabis have been seen.*

In many of the studies we reviewed, subjects experienced mild or moderate side effects that tended to abate as the patient was on the dose over several days or resolve with dose reduction. Serious adverse events—those resulting in death or hospitalization—did occur in the trials; but the type of events and number of them were generally similar in cannabis intervention and control groups. That few serious adverse events caused by cannabis use were observed gives us some degree of confidence as we begin our program. Ongoing attention to and vigilance about potential drug-drug interactions and other issues, however, is merited.

The monograph for Sativex, a cannabis extract product with approximately a 1:1 ratio of THC and CBD provides a useful summary of what is known about side effects and drug interactions. Sativex has

TABLE

**Relevant studies**

QUALIFYING CONDITION	STUDIES REVIEWED
Cancer, if the underlying condition or treatment produces one or more of the following: Severe or chronic pain.....	4 clinical trials 1 observational study (extension of clinical trial)
Nausea or severe vomiting.....	5 clinical trials 1 systematic review and meta-analysis
Cachexia or severe wasting.....	5 clinical trials 1 observational study
Glaucoma	1 clinical trial 2 observational studies
HIV/AIDS	6 clinical trials 1 observational study (extension of clinical trial)
Tourette’s syndrome	3 clinical trials
Amyotrophic lateral sclerosis	1 clinical trial 1 observational study
Seizures, including those characteristic of epilepsy	3 clinical trials
Crohn’s disease	1 clinical trial (concluded, but results not yet reported)
Severe and persistent muscle spasms, including those characteristic of multiple sclerosis	10 clinical trials 3 observational studies (extensions of clinical trials) 4 additional observational studies (including 2 safety registries)
Terminal illness with probable life expectancy of less than one year if the illness or its treatment produces one or more of the following: Severe or chronic pain..... Nausea or severe vomiting..... Cachexia or severe wasting.....	Included in studies accounted for above

been approved by the drug-regulating authorities in Canada, the United Kingdom and a score of other countries. (The monograph, which is similar to an FDA-approved product label, is available at [www.bayer.ca/files/SATIVEX-PM-ENG-30MAR2012-149598.pdf](http://www.bayer.ca/files/SATIVEX-PM-ENG-30MAR2012-149598.pdf).)

*There is a high degree of variation in how individuals respond to cannabis.*

The dose at which side effects show up appears to vary widely among individuals. Similarly, the dose at which symptom reduction occurs also appears to vary substantially. In addition, a substantial proportion of participants in most trials did not get a clinically significant benefit from using medical cannabis.

The conditions with the strongest body of evidence for effectiveness are muscle spasm (studied mostly in patients with multiple sclerosis), cancer-related nausea and vomiting, and cancer-related pain. Yet the studies did not show that medical cannabis was uniformly effective for everyone.

Given the wide variation in how people respond to medical cannabis products, patients should be started at a low dose and the dose should be increased slowly, titrating to symptom reduction or the beginning of intolerable side effects. The studies suggest that increases should be

done several days apart, as increasing the dose too quickly appears to lead to more and more severe side effects. Also, we need to be aware that some patients will experience intolerable side effects before they achieve symptom reduction.

Taken as a whole, the studies, particularly the ones on muscle spasm and pain in multiple sclerosis patients, appear to give this clear message: Clinically significant improvement will be experienced by *some* patients, but not by all. From these studies, we noted that about half the patients see some benefit. A helpful finding is that improvement, if it occurs at all, generally does so within a few weeks of starting therapy. Thus, we know that if a patient doesn't see a benefit within a month or so of beginning therapy, it is unlikely he or she will see one at all. Whether this can be extrapolated to other conditions is unknown because of the short follow-up in nearly all of the studies in the other clinical areas.

*We know even less about the safety and effectiveness of medical cannabis use in children than we do about its use adults.*

Children are not well-represented in the studies. As a result, we have limited evidence about both the effectiveness and potential harms of medical cannabis in this population. Given the legitimate concerns about cannabis' potential for negatively affecting brain development in children and adolescents, this is an important issue. Although more research is needed to determine whether the associations observed between recreational cannabis use in this population and lower mental and psychological functioning are in fact causal and the degree to which findings from high-THC recreational use are relevant to different medical cannabis preparations, caution is in order. At this time, it seems prudent to limit medical cannabis exposure to pediatric and young adult patients with illnesses so life-impacting and poorly managed with current therapeutic options

that it is worth the potential risks to development.

### Final Thoughts

The quality and number of studies is less than what we need for full confidence in our assessment of the potential benefits and harms of medical cannabis. (Because of the difficulty of gaining access to cannabis for trials in the United States, much of the clinical research has been conducted in other countries.) Yet the studies do provide some information to help with decision-making. Basic science, animal and clinical research into the endocannabinoid system and therapeutic uses of cannabis has been growing rapidly in recent years. The Department of Health will update this report periodically to reflect changing knowledge about medical cannabis. **MM**

Tom Arneson is research manager for the Minnesota Department of Health's Office of Medical Cannabis.

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**VIDEO 4: "A Differential Diagnosis for 'Pain'"** Charles Reznikoff, MD, Division of Addiction Medicine, Hennepin County Medical Center, Assistant Professor of Medicine, University of Minnesota Medical School

**VIDEO 5: "What is Buprenorphine?"** Charles Reznikoff, MD, Division of Addiction Medicine, Hennepin County Medical Center, Assistant Professor of Medicine, University of Minnesota Medical School

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**VIDEO 1: "Opioid Addiction and Pain, A Quagmire for Healthcare Professionals"** Marvin D. Seppala, MD, Chief Medical Officer, Hazelden Betty Ford Foundation

**VIDEO 2: "An Editorial on Pain"** Bret Haake, MD, MBA, HealthPartners Medical Group, Regions Hospital

**VIDEO 3: "Pain Psychology, Mental Status Exam, and Non-Opioid Options for High Risk Patients"** Charles Reznikoff, MD, Division of Addiction Medicine, Hennepin County Medical Center, Assistant Professor of Medicine, University of Minnesota Medical School. Adeya Richmond, PhD, LP, Senior Clinical Psychologist, Psychology Department, Hennepin County Medical Center. Sebastian Ksionski, MD, Pain Program/CMC Director, Hennepin County Medical Center

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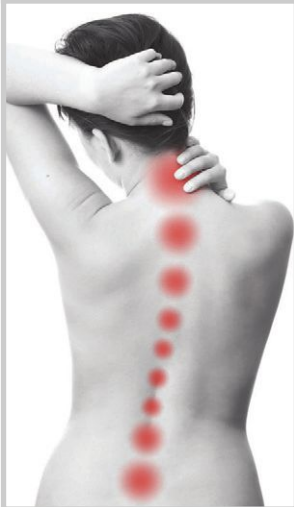
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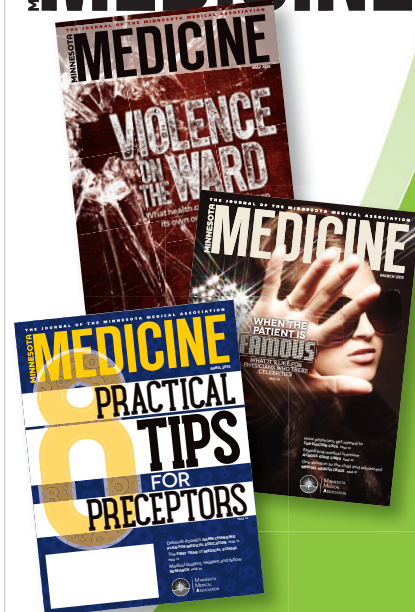
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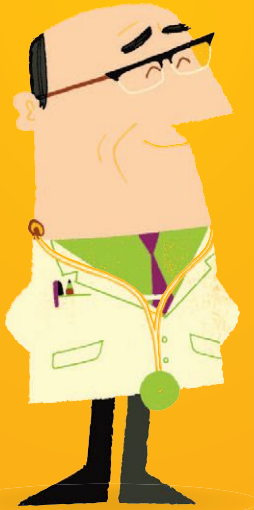


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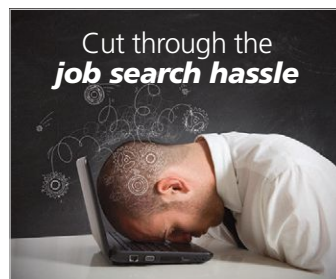
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## The pain

The worst kind isn't necessarily physical.

BY KRISTIN COMSTOCK

**A**nd she knew, probably as much or more so than I did, that it was bad. She knew this was going to be the death of her. She knew things weren't going to get any better.

Yet she insisted the sting from needles, biopsies and the collecting of fluid from her chest wasn't the worst she had felt. It didn't even make it on her list. Nor did she worry about the whirlwind of appointments with surgeons and oncologists, the follow-ups and lab reports. They were nothing but a to-do list.

It wasn't because she didn't understand. She knew she had breast cancer. She could feel the baseball-size lump. She could see the ulcer destroying her skin. She saw the weight dropping off. She felt it getting harder and harder to take a breath as the fluid built up.

But she insisted it wasn't the worst thing she had gone through.

It wasn't the worst pain, she noted, because she had buried her daughter.

And that is the hardest thing anyone could possibly go through. **MM**

Kristin Comstock is a recent University of Minnesota Medical School graduate. She is doing a family medicine residency in Duluth.



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For more information, go to [mnmed.org/ac2015](http://mnmed.org/ac2015)



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