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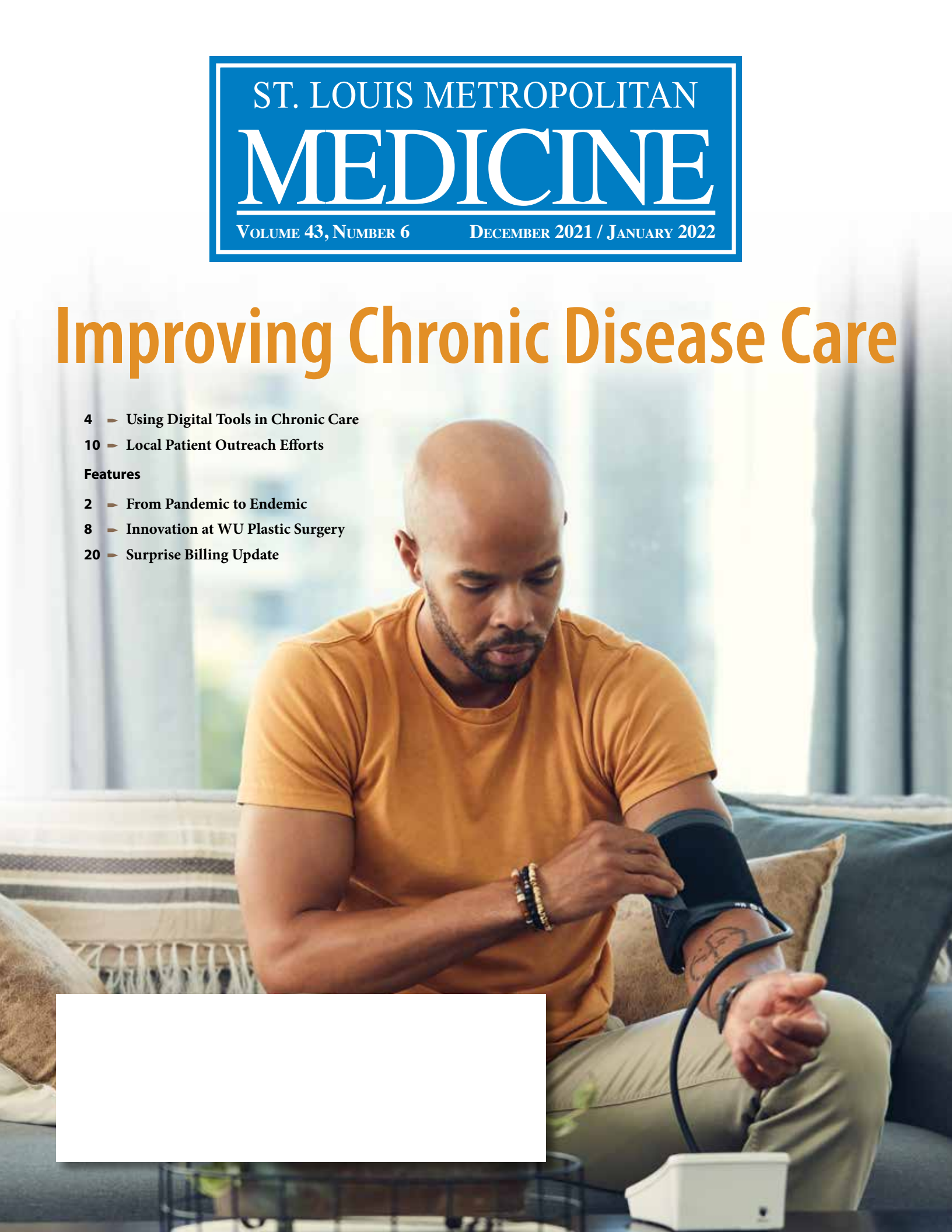
Improving Chronic Disease Care



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A Year in Review: Shifting from Pandemic to Endemic

Jennifer L. Page, MD, President, St. Louis Metropolitan Medical Society 2021

Jennifer L. Page, MD

The AMA supports greater and stronger use of vaccine mandates by public and private sector employers and other organizations.

As I write this article, it has now been over 20 months since March 2020, when the World Health Organization determined that the growing spread of COVID-19 would be officially characterized as a global pandemic.[1] The year that followed challenged our medical community with a public health crisis on a scale that few could even imagine. I am humbled by the efforts of our medical community that fought the pandemic on the front lines, and the research that made remarkable breakthroughs in vaccine and medical treatments. We are starting to shift from pandemic to endemic.

Vaccines remain a significant tool for ending the pandemic. All four major hospital systems—BJC HealthCare, Mercy, SSM Health and St. Luke's—have vaccine mandates for their employees. At the time of this writing, 98% of the Mercy system employees and staff are vaccinated. Mercy includes more than 40 hospitals and 700 clinics in Missouri, Arkansas, Oklahoma and Kansas.[2] According to a survey in June from the American Medical Association, more than 96% of physicians are fully vaccinated against COVID-19, with no significant difference in vaccination rates across regions.[3] The vaccination of health care workers was an imperative first step.

Another recent promising development is the rollout of childhood vaccines. The FDA recommended approval of COVID-19 vaccines for children ages 5 to 11. This paved the way for the campaign for the vaccination of younger children to begin. Expanding this eligibility will significantly decrease community spread of COVID-19. In St. Louis County, the community transmission has been found to be higher among children in this age group, more than any other age group. The average rate of new cases at the time of this writing is highest among 5- to 9-year-olds, at 20.3 cases per 100,000 per day.[4] Covering this age group not only protects families but allows a successful return to the classroom.

New COVID-19 treatments have also recently made big news and could mark a pivotal point in the pandemic. On November 5, Pfizer unveiled a new anti-viral pill that the company says cuts the risk of hospitalization and death from COVID by nearly 90%. Pfizer's pill, with the brand name Paxlovid, could secure U.S. regulatory approval by the end of the year. Pfizer said it plans to submit interim trial results to the Food and Drug Administration before the November 25th Thanksgiving holiday. The trial was stopped early due to its high success rate.[5]

Roadblocks Remain

Despite these advances, there have remained some roadblocks. While officials across the country have launched incentive programs, stressed personal responsibility, and deployed mobile vaccination units—and the medical community has provided ongoing education to encourage COVID-19 vaccine uptake—those efforts have fallen short. As the push to get more people vaccinated against COVID-19 intensifies, many businesses, schools, cities, states and the federal government are turning to vaccine mandates.

As we have learned with the COVID pandemic, there is a political element to public health decisions and public policy decisions that draw on science.

With full approval of the Pfizer-BioNTech COVID-19 vaccine, the AMA has issued a response that supports greater and stronger use of vaccine mandates by public and private sector employers and other organizations for the populations recommended to receive the

vaccine by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices. As the AMA notes, vaccine mandates are not new. All schools have mandated vaccines long before this pandemic, just as have many workplaces like hospitals, doctors' offices and nursing homes.[6]

Missouri currently requires students to be immunized for poliomyelitis, rubella, rubeola, mumps, tetanus, pertussis, diphtheria and hepatitis B. Indeed, as recently as 2014, the Missouri Senate unanimously passed a mandate that students at Missouri colleges had to be vaccinated against meningitis.[7] This was following outbreaks on college campuses. Mandates sent the message that these vaccines were safe and effective.

We have remained united in our calling, as we prevail against this generational challenge and shift from COVID-19 pandemic to endemic.

Medical and religious exceptions are taken seriously by the medical community, and it is imperative that patients discuss these issues with their physician. Physicians have long established deep respect for sincerely held religious beliefs. While many major religious denominations have no objections to COVID-19 vaccines, guidance from the U.S. Equal Employment Opportunity Commission says a religious belief does not have to be recognized by an organized religion. It can be new, unusual or "seem illogical or unreasonable to others," according to the guidance document updated in January 2021.[8]

As with everything else involving COVID-19, religious accommodation issues are complicated, and the legal requirements seem to change day by day. The EEOC in late October presented additional guidance on religious accommodations as applicable to COVID-19 vaccinations. In addition, cases are wending their way through the judicial system, contesting some vaccination mandates because they make no provision for religious exemptions.[9]

In its attempt to curb the pandemic, the Biden administration issued its first national vaccine requirement in July by mandating all federal workers be vaccinated against COVID-19 or face regular testing; that deadline has been extended to January 4. On September 9, the president announced sweeping vaccine mandates including a rule calling for employers with 100 or more employees to require the vaccinations or weekly testing. This rule, enforced by the Occupational Safety and Health Administration, intends to "pre-empt" any state or local requirements that ban or limit an employer from requiring vaccination, face coverings or testing. At the time of this writing, the attorneys general from 11 states, including Missouri, have filed a lawsuit to stop this mandate. A federal appeals court on November 6 ruled in favor of the states, temporarily halting this vaccine requirement for large employers.[10]

As we have learned with the COVID pandemic, there is a political element to public health decisions and public policy decisions that draw on science. Such politicization of the science around vaccines has had a significant impact on vaccine acceptance and availability.

Medical Society Remains Steadfast

During this tumultuous time, the St. Louis Metropolitan Medical Society has remained steadfast, advocating for vaccine acceptance and mitigation efforts.

- We have encouraged masking, vaccinations and support of public health recommendations.
- We have addressed vaccine hesitancy and education efforts.
- We sounded the alarm on early disparities in distribution of the COVID vaccine in Missouri.
- We have been a valuable resource for our community.

As I reflect on the past year to write my final president's column for *St. Louis Metropolitan Medicine,* I am filled with gratitude for my fellow physicians. I have had the rare honor and privilege to be the first president of the St. Louis Metropolitan Society to serve my complete term remotely during a pandemic. Organizations were forced to adapt during the pandemic, and I am proud of the way SLMMS met the challenge to meet the needs of our members and our community. Thank you to Dave Nowak, our executive vice president, for navigating these uncharted waters. Thank you to Jim Braibish for his efforts to provide an outstanding magazine for our members.

Medicine is truly a calling. The Modern Version of the Hippocratic Oath states in part:

> *I swear to fulfill, to the best of my ability and judgment, this covenant:*
>
> *I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.*
>
> *I will prevent disease whenever I can, for prevention is preferable to cure.*
>
> *I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.*

Sharing the scientific knowledge, disease prevention and obligations to our community: These have formed the St. Louis Metropolitan Medical Society's response to this pandemic. We have remained united in our calling, as we prevail against this generational challenge and shift from COVID-19 pandemic to endemic.

Jennifer L. Page, MD, is medical director of the Acute Rehab Program at Mercy Hospital South.

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Chronic Disease Management: The Future Is Now

By David M. Nowak, Medical Society Executive Vice President

David M. Nowak

When the pandemic forced the health care industry to pivot toward telemedicine quickly, it most likely set the stage for quicker adoption of technology for managing chronic diseases.

Statistics from the Centers for Disease Control and Prevention tell us that nearly 60% of adults in the United States have a chronic health issue such as heart disease or diabetes, and many people have two or more chronic conditions, which makes the task of managing them all the more complex. While we live in a world where there is an abundance of modern treatments, effective medications and a robust general knowledge of what is and what is not a healthy choice, the rate of chronic disease in our country continues to increase.

Kal Patel, MD, MBA, is the CEO and co-founder of BrightInsight, a leading global company for biopharma and medtech-regulated digital health solutions, and according to his online bio, has over 20 years of experience in this field.

Dr. Patel recently wrote an interesting article for *Forbes*, summarizing digital health's role in managing chronic disease. He writes about the progress in chronic disease management over the years, and that patients and providers "interested in remote monitoring have numerous options available to maintain a connection with a doctor's office from anywhere."[1]

He adds that "chronic conditions require more seamless and continuous chronic disease management between doctors' appointments. In addition to requiring multiple medications, lifestyle habits often play a factor … and what happens between visits is, arguably, as important as what happens in the office. Tracking behavior and disease progression reliably can help patients adhere to a treatment plan."[1]

Fortunately, today's health care marketplace has a number of digital health tools available or in development, many being created by start-ups and innovation incubators, including several right here in St. Louis. Wearables, remote patient monitoring and other devices can assist with condition-specific factors. Activity trackers, medication reminders and monitoring equipment record data in real time in between doctor visits.

However, Patel concludes that challenging the adoption of many of these devices is the fact that "there are few tools that work across conditions, even though two out of five adults are managing two or more chronic diseases. A unified patient experience across multiple conditions that are integrated into the clinical workflow is critical to driving adoption and scale."[1]

Responding to that need, AstraZeneca is developing Amaze, a digital platform designed to simplify chronic disease management. Launched earlier this year, the company is collaborating with Massachusetts General Hospital to test a mobile application that integrates third-party platforms collecting data for patients based on their disease states, in real time. The initial clinical studies focus on asthma, heart failure and COPD, with more broad applications for diabetes and renal failure planned. The tools are designed to share information across the various health teams caring for the patient, keeping everyone in the loop.[2]

Innovation in the biopharma industry is advancing at a rapid race. Novo Nordisk is studying digital therapeutics to help people manage insulin dosage and diabetes. One Medical is developing integrations of its technology platform to allow patients to share health data from multiple monitoring devices directly with their care providers, with the goal of making medication and treatment plan adjustments immediately.[3]

One unforeseen advantage coming out of the COVID-19 pandemic could very well be broader acceptance of this technology by both providers and patients, as well as obtaining reimbursement for services. When the pandemic forced the health care industry

to pivot toward telemedicine quickly, it most likely set the stage for quicker adoption of technology for managing chronic diseases.

One remaining challenge may well be interoperability. The lack of interface between different medical records and the inability to communicate effectively between patients, their physicians, and their social workers remains a barrier.[4] Tight integration not only improves data integrity, but enhances the overall experience for both providers and their patients.

For digital health solutions to help manage chronic disease, the future is now. It's exciting to read about seamless strategies to improve overall care that are on the not-too-distant horizon. Digital health solutions will help physicians deliver services and preventative care, while patients can better manage their chronic conditions and stay in closer communication with their doctors. In other words, modern technology is delivering a win for everyone.

Some Closing Thoughts

As we approach the end of the second year of the COVID-19 pandemic, I thank everyone for their patience and flexibility over these past 21 months. While we have shifted much of our SLMMS advocacy emphasis toward combating vaccine hesitancy, encouraging masking and supporting public health initiatives during the pandemic, our Council and leadership have continued to oversee operations of the Medical Society. We've continued virtual Council and committee meetings, and provided virtual educational opportunities and legislative updates with good attendance, sustained interest and success.

A survey of our membership in August found that many are anxious to return to in-person learning and events, while others are skeptical of moving too fast, too soon. When the delta variant caused a surge in cases in late summer, the SLMMS Council voted to continue virtual meetings through the end of 2021. This again forced the cancellation of our Hippocrates lecture and dinner meeting as well as our annual holiday party. With the goal of having a successful in-person event, we have postponed our annual meeting and installation dinner from January to April next year. We'll install our new leaders virtually in January, but hope to celebrate with them and our award recipients in the spring.

Second, please allow me to remind any of you who have not paid your 2022 SLMMS dues to submit them before the end of the year. Initial dues billing went out in September, and the early response was most encouraging. Reminder invoices were mailed in November, and your prompt payment saves valuable staff time and the need for follow-up notices. We're still struggling with membership following the COVID pandemic and hope you'll continue your support, which allows us to work for you and the practice of medicine.

Lastly, I'll end this column as I do every December—extending my gratitude to our members for allowing me the opportunity to work for you. As I conclude my ninth year as your executive vice president, I so clearly see the need for and the importance of organized medicine, and I'm thankful you share that vision. I wish all of you a joyful holiday season and a healthy and happy new year.

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SLMMS Annual Meeting and Installation Dinner Rescheduled for April 23, 2022

It is our hope that our 2022 SLMMS Annual Meeting and Installation Dinner can be an in-person event, especially following the cancellation of the 2021 event due to the COVID-19 pandemic. Out of an abundance of caution, the SLMMS Council has decided to postpone the event from the previously announced January date to a new date: **Saturday, April 23, 2022**.

"The decision was made due to the continued cancellation and/or postponement of many winter events, as well as reluctance to attend large gatherings, and concerns that we may see a spike in cases this winter," stated Dave Nowak, SLMMS executive vice president. "The additional three months will provide extra time for increased vaccinations, boosters, and hopefully, less community transmission of COVID-19."

The 2022 Annual Meeting and Installation Dinner is planned for the Living World at the Saint Louis Zoo. Watch for more information about sponsorships in January. All SLMMS members will receive their invitations by mail next February or March.

Physician Home Mortgage Program for SLMMS Members

SLMMS is pleased to announce another new member-only benefit that adds value to your Medical Society membership. Through a newly created relationship, Commerce Bank is now offering SLMMS members a mortgage loan program designed especially for physicians.

The Physician Home Mortgage Program can streamline the mortgage process, reduce your costs and includes a dedicated banker to meet your specific needs. The offer applies to home purchases and refinances of your primary, secondary or vacation homes.

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"Commerce Bank is excited to be a new member benefit partner with SLMMS," said Kathleen Springer, private banking team leader and senior vice president. "We operate as a 'Super Community Banking' organization offering a broad array of sophisticated products that address the needs of consumers, business and wealth management. Our commitment to the St. Louis health care community is demonstrated with our dedicated Commerce Healthcare group."

"As a member of SLMMS, you will have direct access to our mortgage resources and a $500 credit toward closing costs," he added. "Whether it is your first home, your forever home or vacation home, we will ensure that you have efficient and local attention to your needs."

Visit slmms.org for more information or to download the program flyer. For information or to utilize the member benefit, contact Greg Benton, Commerce mortgage banker, at 314-746-5188 or Greg.Benton@CommerceBank.com.

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Wanted: Your Ideas for Resolutions

Want to impact the practice of medicine? One of the best beginning steps is to write a resolution. As we prepare for the Missouri Legislature to convene in January, it's time to begin thinking about drafting resolutions for the 2022 annual convention of the Missouri State Medical Association (MSMA), scheduled for April 1-3 at the St. Louis Airport Renaissance Hotel.

Resolutions are a wonderful illustration of organized medicine working for physicians. If you're considering a topic for a 2022 resolution, even if it's still in its conceptual stage, SLMMS invites you to bring it forward in accordance with the following schedule:

- For a resolution to be introduced and sponsored by SLMMS, it must be presented and reviewed twice by our body of delegates. The first opportunity will be at the SLMMS Delegates' Briefing Session on **Tuesday, January 18, 2022 at 6:00 p.m.** virtually via Zoom. All District 3 delegates will receive an email announcing this meeting, but all SLMMS members, including medical students, are invited to participate.
- Resolutions drafted or accepted at that meeting will go forward for a second review to be held in conjunction with the monthly SLMMS Council meeting on **Tuesday, February 8, 2022 at 6:00 p.m.** Resolutions receiving final approval at this meeting will be submitted as sponsored by SLMMS.
- The deadline for submitting resolutions to MSMA for inclusion in 2022 convention materials is **Wednesday, February 16, 2022 at 5:00 p.m.**

If you are a member of MSMA, you are free to submit your resolution on your own, but for it to be reviewed and sponsored by SLMMS, the above-referenced process must be followed.

The SLMMS Political Advocacy Committee will be meeting in mid-December to draft the Society's 2022 Legislative Priorities. Please watch the SLMMS website for postings reviewing the priorities as well as a link to MSMA's Guidelines on Resolution Writing. If you are researching or planning a resolution, please notify the SLMMS office for it to be included in the January 18 meeting agenda. If you have questions, or if you wish to register for the annual Delegates' Briefing Session, please contact Dave Nowak at dnowak@slmms.org and the Zoom link and meeting materials will be forwarded to you.

Missouri Legislative Update and 2022 Preview

SLMMS members gained insight on key health care issues in the Missouri Legislature during a September 21 program presented by Heidi Geisbuhler Sutherland and Shantel Dooling, the Missouri State Medical Association's lobbying team.

They reviewed the 2021 session that included dozens of COVID-related bills, as well as leftover legislation from 2020's shortened session. It was a big year for health care, most notably the passage of a statewide Prescription Drug Monitoring Program, along with all of the budgeting and legal issues surrounding Medicaid expansion in Missouri. A notable win for medicine was the passage of COVID-19 liability legislation; however, Missouri also passed a bill limiting the powers of local public health agencies in response to pandemic mandates like masks and restaurant shutdowns.

The lobbying team also reported on various scope-of-practice expansion attempts by nurse practitioners, physical therapists and others that were defeated in 2021. A House bill that would have weakened childhood immunization requirements was also defeated, yet the COVID-19 vaccine passport prohibitions bill was passed. Several public health bills were also front and center for physicians, including hearing aids for kids and mental health parity legislation, both of which were passed.

SLMMS asked the MSMA lobbying team for its thoughts about the upcoming 2022 session:

"Every legislative session has its twists and turns, but MSMA expects the 2022 session to be a particularly curvy road," said Sutherland. "The first several weeks of session will be dominated by the congressional redistricting process. Once redistricting is hammered out, the legislature will set its sights on a variety of issues that range from critical race theory to COVID-19 protocols."

"We already know of several bills that have the potential to affect the house of medicine. One controversial piece of legislation would prohibit employers from requiring their employees to get the COVID-19 vaccine. Another proposed

Photo credit: Tim Bommel/Missouri House of Representatives

bill would mirror the Texas abortion law passed earlier this year," Sutherland continued.

"MSMA will try to resurrect last year's down-coding legislation and test the waters for a bill that would make the prior authorization process less onerous for physicians and staff," she added. "We'll also likely revisit several public health initiatives from 2021 like a statewide texting-while-driving ban, improved car seat regulations for children, bleeding control kit access and further restrictions on e-cigarettes and vapor products."

MSMA plans to again host virtual "Legislative Lunches" with Missouri lawmakers during the coming session, and encourages everyone to participate in the Annual White Coat Day in March.

For more information about legislation or MSMA policy, contact the MSMA office at (573) 636-5151, or email Sutherland (heidi@msma.org) or Dooling (shantel@msma.org).

A Year in Review … *continued from page 3*

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Technology and Innovation at Washington University Plastic Surgery

Current investigations offer improvements in reconstructions, pressure sore prevention, vascular attachment and more

By Justin Sacks, MD, MBA, FACS; Will Moritz, MD, and Hayden Schott, BS

The Division of Plastic and Reconstructive Surgery at Washington University School of Medicine has played a critical role in developing the field locally, nationally and globally. It is a historic clinical training and research program which turned 100 years old in 2020. We have 20 faculty members, of which three are full-time PhDs engaged in cutting-edge clinical, basic science and translational research. This advanced approach has led some of our faculty members to focus specifically on technological advances in the field of plastic and reconstructive surgery.

Plastic and Reconstructive Surgery covers head-to-toe cancer and traumatic reconstruction along with cosmetic surgery. We, as plastic surgeons, operate all over the body. Something that genuinely makes our specialty unique is its ability to innovate and invent. Frequently, this innovative spirit manifests itself as discovering new procedures or technologies, as occurred with the development of microvascular surgery for cancer and trauma reconstruction or the creation of a new type of bandage to reduce scar formation. We currently have several new ideas in our division that are being investigated from "bench to bedside." This is the concept of taking something from the lab to use in the human being in a clinical setting.

Dr. Justin Sacks

Justin Sacks, MD, MBA, FACS, is the Shoenberg Professor and Chief of the Division of Plastic Surgery in the Department of Surgery at Washington University School of Medicine.

Dr. Will Moritz

Will Moritz, MD, is a graduate of the University of Missouri-Columbia School of Medicine and a current post-doctoral translational research fellow in the Division of Plastic and Reconstructive Surgery at Washington University.

Hayden Schott

Hayden Schott, BS, graduated with a degree in biomedical engineering from Washington University in 2021 and currently works with John Felder, MD, on limb salvage research and device development as a clinical research assistant.

Plastic and reconstructive surgery is a fantastic specialty that helps transform patients with congenital anomalies, the ravages of cancer and trauma, and those who would like to look younger and more youthful.

Following are four innovative investigations under way in the Plastic Surgery Division:

Perfusion Assessment Using Wireless Near-Infrared Technology

Many plastic surgeons have adopted near-infrared sensors, which use near-infrared light to measure tissue oxygen saturation, for post-operative monitoring of free tissue transfers for breast, head and neck and limb reconstruction. These sensors have good sensitivity and specificity for vaso-occlusive events when blood supply stops. However, patient repositioning or ambulation can lead to spurious signal loss or change as traction is placed on the cord connecting the sensing device to the visual display, leading to distress for both the surgeon and patient.

Mitchel Pet, MD, has been working with collaborators at Northwestern University to develop a new wireless device for free flap monitoring. Similar to standard technology, it employs near-infrared spectroscopy to measure tissue oxygen saturation. However, this device is waterproof and completely wireless. This device was tested in a porcine musculocutaneous model of arterial and venous occlusion and detected both ischemia and venous congestion. Further research will hope to validate this as a post-operative monitoring device among patients who receive free tissue transfer at Barnes-Jewish Hospital.

Decreasing Pressure Sores Using a Low-Profile Flexible Device

The Mercury Patch, a single-use, wireless device capable of continuous bedside pressure monitoring, has been developed by Matt MacEwan, MD, PhD, from Washington University, John Rogers, PhD, of Northwestern University, and Justin Sacks, MD.

Dr. Moritz, left, and Dr. Sacks in front of the entrance to the Plastic Surgery Research Labs.

This device was created for pressure injury prevention in hospitalized patients. Preliminary data have shown that the device is capable of monitoring physiologically relevant pressures across independent force sensors.

With funding from both the Washington University Big Ideas competition and the Leadership and Entrepreneurship Acceleration Program (L.E.A.P.) at Washington University, Amanda Westman, PhD, a faculty member in our division and lead investigator on the project, has begun enrolling patients in a clinical trial designed to validate the safety and effectiveness of these devices in measuring pressures during lengthy operative procedures. We hope to soon test the compatibility of these devices with the clinical workflow and demonstrate a correlation between pressure "dose" and ulcer development.

Putting Blood Vessels Together Without Sutures

Vasolock is a sutureless vascular anastomotic device developed by myself and collaborators during my previous tenure at Johns Hopkins University in Baltimore, Md. Using traction, the device can couple both arteries and veins in less than one minute without the assistance of specialized instruments.

Working with assistant professor of surgery Xiaowei Li, PhD, in our plastic surgery division, we have begun testing the devices in a large animal model of arterial and venous anastomosis. Additionally, Dr. Li has started benchtop experiments to modify the surface of these implants to both prevent thrombosis and encourage endothelialization, potentially allowing for long-term placement. We recently applied for a DOD grant with our collaborators at Johns Hopkins University and Walter Reed National Military Medical Center to develop a version of Vasolock that can be deployed with combat surgical teams for wartime vascular injuries.

Synthetic Hernia Mesh Requiring No Sutures

Annually, there are approximately 400,000 operations to repair the ventral hernias produced by failed laparotomy closures. The current mesh designs that exist to solve this problem exhibit inadequate mechanical properties for the high-demand environment of the abdominal wall.

With his extensive clinical knowledge of soft tissue healing, John Felder, MD, is currently developing innovative technologies to increase the rate of successful primary closures. Through work with his collaborators, he has successfully prototyped a preliminary device that exceeds the requirements of this high tensile stress environment. Validation of the device is underway with benchtop stress tests.

Plastic and reconstructive surgery is a fantastic specialty that helps transform patients with congenital anomalies, the ravages of cancer and trauma, and those who would like to look younger and more youthful. The faculty, scientists and research fellows in the Division of Plastic and Reconstructive Surgery at Washington University School of Medicine are pushing the needle of innovation forward. Every day we come to work, we look to make our patients better with surgical procedures that will change their lives. We also innovate how we carry out these procedures and use technology to make these procedures safer, more efficient and better for all of our patients in St. Louis and the world around.

Mercy Names Physicians to Senior Positions


Dr. David Meiners

David Meiners, MD, has been named president of Mercy Hospital St. Louis, its first physician leader. He most recently served as chief administrative officer for Mercy Clinic and as surgery department chair in Mercy's eastern Missouri region.


Dr. Jeff Ciaramita

Jeff Ciaramita, MD, has been appointed senior vice president and chief physician executive of Mercy Clinic, encompassing more than 4,000 providers across the Mercy system. He has been president of Mercy Clinic St. Louis since 2019, and was holding the system role on an interim basis.

Improving Chronic Disease Care

Area health systems and health centers target efforts for patients with diabetes, hypertension and other conditions

By Jim Braibish, St. Louis Metropolitan Medicine

Chronic disease is the costliest drain on the U.S. health care system and the health of Americans.

Six in 10 adults in the U.S. have chronic diseases, a broad group of conditions that include hypertension, diabetes, cancer, obesity, arthritis, stroke, multiple sclerosis and others. Four in 10 U.S. adults have two or more chronic conditions. Chronic diseases are defined broadly as conditions that last one year or more and require ongoing medical attention or limit activities of daily living or both.[1]

It is estimated that 90% of the nation's $3.8-million annual health care expenditures are for people with chronic diseases and mental health conditions.[2] Examples of the impact:

- More than 868,000 Americans die of heart disease or stroke every year—one-third of all deaths.
- Each year in the U.S., more than 1.7 million people are diagnosed with cancer, and almost 600,000 die from it.
- Over 34 million Americans have diabetes, and another 88 million have prediabetes.
- Obesity affects 19% of children and 42% of adults.
- Arthritis affects 54 million adults in the U.S. each year.[2]

Many chronic diseases can be prevented or reduced in severity with lifestyle changes including improving diet and exercise and by eliminating risky behaviors such as tobacco use and excessive alcohol consumption.

Health systems and community health centers in the St. Louis area are conducting pro-active efforts to reach patients with hypertension, diabetes and other conditions, in an effort to increase the number of patients who maintain their numbers within healthy ranges.

Mercy Clinic

Mercy recently rolled out a "Diabetes Automation" initiative at primary care practices across its four-state territory. Targeting patients with diabetes, the system identifies those who have not had regular hemoglobin A1c tests at their prescribed intervals. The patients are sent reminders via text message and are assisted in obtaining a test.

Initial data from a September 2021 pilot showed that 425 messages were sent to Medicare Advantage diabetic patients who either had an A1c of 8 or above in the past 90 days, or who had not had an A1c test in the past 365 days, according to Carolyn Koenig, MD, chair of quality, safety and value for Mercy Clinic East Communities, and an internal medicine physician. Among the findings:

- 20% of patients receiving outreach obtained an A1c test.
- 52% of those having A1c drawn completed the testing within 5 days of outreach.
- Approximately 48% of those who obtained tests had A1c readings of 8 or below.

It is estimated that 90% of the nation's $3.8-million annual health care expenditures are for people with chronic diseases and mental health conditions.

"To help monitor home readings, we have developed a remote biometric monitoring encounter where patients can submit their home readings through MyChart."

This is just one of many initiatives under way. Another Mercy Clinic effort targets patients with poor diabetes control as defined as an A1c above 9. A central diabetes nurse care team works with patients toward reaching their control goals. "They partner with the PCP or the central team's nurse practitioner to adjust insulins and other medications and get patients set up for continuous glucose monitoring when appropriate as well," Dr. Koenig said.

For patients with hypertension, Mercy Clinic has made ongoing efforts. For several years, they participated in the American Medical Group Association's "Measure Up Pressure Down" program. "We started at 60% control for hypertension, but now I am happy to say we are at 80%. Mercy is one of the highest ranking health systems in this initiative," Dr. Koenig added.

Currently, Mercy Clinic has an effort with primary care practices to engage medical assistants as important members of the team. They are reinforced on how to use proper technique in measuring blood pressure, and are encouraged to teach patients to take their pressures at home.

"To help monitor home readings, we have developed a remote biometric monitoring encounter where patients can submit their home readings through MyChart so they can be averaged readily and more easily populate the EPIC system and count for quality metrics. It works especially well when patients have a Bluetooth-enabled blood pressure cuff, as the readings will flow automatically into the EHR," Dr. Koenig explained.

She also noted that the U.S. Surgeon General's October 2020 report called for greater self-monitoring of blood pressure.

For patients with diabetes who are insured through Medicare, Medicare Advantage or select commercial programs, there is a team of RN care managers and social workers who engage with patients via MercyCare Connect. This is a text message reminder program to monitor blood sugars and other metrics developed in conjunction with the St. Louis startup company CareSignal (formerly Epharmix).

Care for chronic conditions is part of an overall focus on population health in Mercy Clinic. At the system level, Mercy has a Population Health Core Team providing direction for primary care practices.

Dr. Koenig explained, "Instead of just focusing on the set of patients who are engaged and able enough to come see you in the office, we look for those who have trouble coming in due to physical or social reasons and make sure they are being seen at least once a year either in person, virtually or with an ambulatory nurse practitioner team we have."

She added that they use data to hone in especially on patients with chronic disease states like heart failure, diabetes, osteoporosis or emphysema. "We reach out to them when they have a gap in care, could benefit from other specific medications or support from the greater care team of care management nurses, social workers or dieticians."

BJC Medical Group and Washington University

Among several initiatives under way, BJC Medical Group is testing a remote patient monitoring program for patients with diabetes, hypertension, heart failure and/or chronic obstructive lung disease. In both programs, patients receive a pack of home-based sensors that measure patients' biometrics, such as blood pressure, glucose values, weight and lung function. This information is then transmitted back to the care teams, who monitor it for any signs of disease worsening.

"Early signs indicate that patients and care teams like the program," said Thomas Maddox, MD, vice president, digital products and innovation at BJC HealthCare. "We will be measuring its ability to prevent worsening disease and the need for either ED visits or hospitalizations. If it does, then we will start scaling it to all our patients who would benefit from the program."

A similar program is being tested by the Cardiovascular Division at Washington University School of Medicine, focusing on heart failure patients.

Continued

At the Women & Infants Center—a collaboration between Barnes-Jewish Hospital, Washington University Physicians and St. Louis Children's Hospital—remote monitoring is being used to assist new mothers with hypertension in bringing their pressures under control. Twice a day, for 14 days, these moms receive a text message instructing them to take their blood pressures and submit the results via text. The texts are managed by a HIPAA-compliant platform. Launched in April 2020, the remote monitoring program worked with more than 1,000 moms in its first year.

Community Health Centers

Because they serve a low-income, inner city, largely minority population, community health centers see a high proportion of patients with chronic conditions such as diabetes, hypertension and obesity.

"We take care of a population at high risk for multiple medical conditions. The social determinants of health can make life hard and thus staying healthy hard," said Melissa Tepe, MD, chief medical officer for Affinia Healthcare, one of the area's largest community health centers, serving some 43,000 patients.

Affinia Healthcare works with the state Medicaid program to establish a patient-centered medical home for persons with hypertension, diabetes or obesity. "This enables us to have nursing and behavioral health staff to connect with patients between visits," Dr. Tepe explained.

For uninsured patients, Affinia Healthcare utilizes community health workers along with nurses to help patients navigate services and identify healthy options.

Affinia Healthcare currently tracks about 3,200 diabetic patients and 3,700 with hypertension. About 61% of diabetic patients are maintaining A1c levels below 9, and 71% continued to receive diabetic foot exams during the pandemic. About 50% of hypertension patients are reported within controlled levels.

Chronic Disease and Mental Health

Many chronic illnesses bring physical limitations, particularly in the case of stroke, diabetes, kidney disease and neurological disorders such as Alzheimer's or Parkinson's. It is estimated that up to one-third of individuals with a serious medical condition have symptoms of depression.[3]

At Affinia Healthcare, behavioral health is integrated into primary care. "In the Medicaid health home, our nurses and social workers go through special training focusing on the mental health toll of chronic conditions. Depression and anxiety are common. They work with patients to create great health habits," Dr. Tepe said.

"The social determinants of health can make life hard and thus staying healthy hard."

For the uninsured portion of their patient population, there is a "warm handoff" to a behavioral health provider on staff if needed.

Mercy Clinic East has a behavioral health collaborative care program in which behavioral health specialists work with the primary care provider and psychiatrist. "We have seen a dramatic decrease in depression scores with this program," Dr. Koenig said.

The Department of Orthopedic Surgery at Washington University is testing a program among its chronic pain patients to identify and treat anxiety and depression. Dr. Maddox described it: "These mental health conditions are very common in chronic pain and are often underdiagnosed and treated. Our program systematically screens for anxiety and depression through electronic questionnaires, then connects affected patients to an app-based counseling program. The program has shown some early, promising signs that anxiety symptoms can be effectively identified and treated with this approach."

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Midwest Health Hub: A New Information-Sharing Resource

Do you have a story to share? Has your practice implemented innovative strategies to improve care delivery, patient engagement, affordability or health outcomes? Are you curious about what health care purchasers, providers or others are doing? Would you find it helpful to know how the local health care market is responding to current challenges surrounding COVID-19, deferred care or changing market dynamics?

The Midwest Health Initiative (MHI) has launched a communication tool, the Midwest Health Hub, to strengthen connections and share knowledge across our health care community. It seeks to enable diverse health care partners to track regional progress in making health care work better for patients, providers, purchasers and our community, and to expedite improvements. Powered by an artificial intelligence platform, with content sourced from local partners, the personalized newsfeed can be customized to reflect a subscriber's interests and be delivered on a schedule of your choosing. Topic areas include:

- Patient engagement and consumerism
- Innovations in care delivery and payment
- Health care quality and patient safety
- Health care cost and affordability
- Employer health benefit strategies
- Health policy and legislation
- Community health and well-being
- Pharmaceutical industry news
- Data and transparency
- Networking news and events

"Whether you represent a provider, heath plan, purchaser of health care, public health, research or other organization, we are interested in your learnings, strategies and successes," said Louise Probst, executive director of the Midwest Health Initiative. "The Midwest Health Hub will become more relevant as you become engaged. Help us build a strong hub for regional health care connections by sharing a story or recommending a noteworthy article."

The opportunity to create the Midwest Health Hub came to MHI through a partnership with similar regional health improvement collaborative organizations (RHICs) in other communities. MHI had been looking for a simple and efficient communications tool to stay connected with its partners. The concept quickly gained favor for its ease of use and ability to support MHI's mission to bring together and share information with those that provide, pay for and use health care.

Through a contract spearheaded by the Network for Regional Healthcare Improvement, MHI joined with four other communities to license a communications platform from Cerkl, an award-winning Cincinnati communications firm. While MHI also contributes articles, most of the content comes from community partners, and much of the administrative work is reliably done by Cerkl's computer system.

MHI is pleased that the newsfeeds are increasingly populated with local content and currently reaches over 4,000 community partners. Click and open rates are increasing.

The voice of practicing physicians has always been important around MHI's table; and as such, it is eager to feature content that highlights improvement and innovative efforts from practicing physicians. MHI is grateful for the strong partnership it enjoys with SLMMS and appreciates the insights and leadership it has received from SLMMS leaders.

MHI is asking physicians to help shape the Midwest Health Hub's content as well as become engaged readers. Please submit your lessons learned or success stories regarding progress to enhance health care and well-being in our region to info@midwesthealthinitiative.org.

View the Midwest Health Hub at https://bit.ly/MidwestHealthHub.

The Midwest Health Initiative is a St. Louis-based, 501(c)(3) nonprofit health-improvement collaborative dedicated to improving health and health care across Missouri and its bordering communities. MHI's leaders and partners represent individuals from all areas of health care: physicians, hospitals, health plans, labor unions, business, government, public health professionals and consumers. SLMMS maintains a representative on MHI's board. http://www.midwesthealthinitiative.org/.

Government Issues New Protocol for Health Care Fraud Self-Disclosure

Physicians should be aware of expanded requirements

By Denise Bloch, JD

On November 8, 2021, the Office of Inspector General (OIG) issued a new protocol for persons or entities[1] wishing to voluntarily self-disclose self-discovered evidence of potential fraud under the Health Care Fraud Self-Disclosure Protocol (SDP). SDP gives individuals an opportunity to settle potential exposure for penalties while also avoiding costs and disruptions normally associated if the government undertakes an investigation and civil or administrative litigation. The following discussion provides a general overview of the updated SDP.

The update made the following changes:

- Increased minimum amounts required to settle under the SDP matching new statutory minimum penalty amounts.
- Required SDP submissions through HHS-OIG's website.[2]
- Added references to OIG's 2019 Grant and Contract Self-Disclosure Protocols.
- Corporate Integrity Agreement (CIA) Reportable Events can be disclosed under the SDP.
- Department of Justice (DOJ) sometimes settles SDP cases.
- Disclosers must include damages to each affected federal health care program and the sum of all damages.
- Made technical changes to statistics, terminology and background facts.

Denise Bloch

Denise Bloch, JD, is Of Counsel at the law firm of Evans & Dixon, LLC, where she regularly advises health care clients on regulatory and risk issues, including fraud and abuse, HIPAA privacy, compliance, licensing, reimbursement and credentialing matters. She is the past chair of the Missouri Bar Health and Hospital Administrative Law Committee. She can be reached at dbloch@evans-dixon.com or (314) 552-4017.

The following did not change:

- Timelines and content requirements for SDP
- Methods for calculating damages
- Timely settlement with a lower multiplier and an exclusion release

The following provides a brief overview of the OIG notice of the amendment updates and the renaming of the Provider Self-Disclosure Protocol.

Importance of Disclosure

The OIG emphasizes the importance of disclosure—along with the health care industry's legal and ethical duty to both detect and prevent fraudulent and abusive activities—to ensure the integrity of federal health care programs.

Benefit of Disclosure

Good faith disclosures:

- Serve to demonstrate robust and effective compliance programs, allowing the OIG to release disclosing parties from permissive exclusion without requiring any integrity measures.
- Allow the OIG to use a minimum multiplier of 1.5 times the single damages, in contrast to the multiplier a government-initiated investigation would require. However, the multiplier used depends on the facts of each case, and some may warrant a higher multiplier.
- May allow for a suspension of the obligation to return overpayments until a settlement agreement is entered, or the person withdraws or is removed from the SDP.

Eligibility Criteria and Guidance

- **Who may use the SDP.** Eligible are health care providers, suppliers or other persons subject to OIG's Civil Money Penalties (CMP).[3] The SDP is not limited to a single industry, as persons may disclose potential violations of the federal anti-kickback statute[4] (AKS), triggering CMP liability. Persons making a submission to the SDP are "disclosing parties," who should disclose conduct the disclosing party may be liable for, but should not use the SDP to disclose conduct of another, unrelated party. If disclosing parties are already under a government

inquiry, they still may use the SDP, but it must be a good faith disclosure and not an attempt to avoid the inquiry. Disclosing parties under a corporate integrity agreement (CIA) may use the SDP, but must (1) disclose they are under the CIA, (2) notify their OIG monitor, and (3) disclose to the OIG as a reportable event.

- **Conduct eligible for the SDP.** A disclosing party may use the SDP, if in the disclosing party's reasonable assessment, the matter potentially violates a federal criminal, civil or administrative law for which CMPs are authorized. The disclosure must acknowledge the conduct is a potential violation, and explicitly identify the law potentially violated.
- **Conduct ineligible for the SDP.** If the matter does not involve potential violation of federal criminal, civil or administrative law for which CMPs are authorized, the SDP is not proper. In such cases, the disclosure should be made to CMS or the contractor under the payer's voluntary refund process. The SDP is not available 1) to request an Advisory Opinion;[5] 2) to disclose an arrangement involving only liability under the physician self-referral law[6] (Stark law[7]) unless there is also a potential violation of the AKS for the same arrangement; or 3) for conduct more appropriately disclosed through OIG's grant or contractor self-disclosure programs.[8]
- **Tolling the statute of limitations.** To use the SDP, the disclosing party must agree to waive and not plead statute of limitations or other similar defenses in any administrative action filed by the OIG relating to the disclosed conduct, unless the defense would have been available initially.
- **Corrective action.** The disclosing party must ensure the improper conduct ended or corrective action will be taken to terminate the conduct within 90 days of the SDP submission.

Content of Submissions

- **All disclosures** – Disclosing parties conduct internal investigations and report the findings in SDP disclosure, or if not completed, certify the investigation will be completed within 90 days. Disclosures must be submitted to the OIG's website,[9] and include mandatory information:
  - Disclosing party and their representative: name, address, type of provider, provider identification number(s), tax identification number(s), and government payers receiving the claims
  - Owner or related parties of the entity or relationship of disclosing party
  - Concise statement of all details of the conduct, including the type of claims or other conduct, the time frame, names of other persons involved and their roles
  - Federal, civil or administrative laws involved
  - Federal health care programs affected
  - Estimate of the damages
  - Corrective action taken upon discovery of the conduct
  - Statement of knowledge of pending government inquiry
  - Authorized individual to settle the matter
  - Certification that the information is truthful and a good faith effort to assist OIG in resolving the matter
- **Requirements for conduct involving false billing** – This requires a review to estimate the improper amount paid by the government program to calculate damages. Review guidelines require using either:
  - All claims; or
  - Statistically valid random sample of the claims.
- **Requirements for conduct involving excluded persons** – The parties disclose employment of, or contracting with, persons on the OIG's List of Excluded Individuals and Entities (LEIE)[10] and specific information with the disclosure. Damages are calculated based on services provided, or the excluded party's cost of employment.
- **Requirements for conduct involving the AKB and Stark Law** – Stark Law violations alone are ineligible for SPD, and conduct must violate both laws to be eligible for SPD. Specific information to understand potential liability from the relationship and details of the conduct, as well as the damage calculation estimate should be included.

Resolution

- **Settlement process considerations**
  - Cooperation, realistic expectations and clear communication
  - OIG coordination with DOJ
  - OIG coordination with SRDP
  - Minimum settlement amounts
  - Ability to pay
  - Overpayment reconciliation
  - FOIA implications

Conclusion

The SDP process is complex, and potential settlements may be costly. Recent self-disclosures resulted in CMPs, ranging from $10,000 for employing an excluded employee to $7.1 million for submitting DME claims for locations not enrolled in Medicare. Health care providers are obligated to investigate potential fraud. Accordingly, it is always important to engage legal counsel to determine the best way to proceed with potential fraud investigations or a disclosure, if needed.

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CMS Innovation Center Launches "Bold New" Strategy

Is value-based reimbursement becoming a priority once more?

By Todd Zigrang, MBA, MHA, CVA, ASA, FACHE, and Jessica Bailey-Wheaton, Esq.

When President Joe Biden was elected in 2020, there was much anticipation and speculation regarding what his election would mean for the U.S. health care industry in the coming years.

As an ardent supporter of the Patient Protection and Affordable Care Act (ACA) who campaigned on offering a public insurance option similar to Medicare, many in the health care industry assumed that the Biden administration would be a strong proponent of continuing the shift to value-based care. That shift was largely spurred by former President Barack Obama with the passage of the ACA.[1]

However, due to the COVID-19 pandemic and other health care priorities, Medicare's value-based payment models have largely taken a backseat in the administration's first year in office. Nevertheless, recent statements from leaders of the Center of Medicare & Medicaid Innovation (CMMI) indicate that value-based reimbursement is becoming a priority once more.

CMMI was created by the ACA,[2] "with the goal of transitioning the health system to value-based care by developing, testing and evaluating new payment and service delivery models in Medicare, Medicaid and the Children's Health Insurance Program (CHIP)."[3,4] CMMI "has a growing portfolio testing various payment and service delivery models that aim to achieve" higher quality care at lower costs, reaching almost 28 million patients and over 528,000 health care providers and plans between 2018 and 2020.[3,5] Although the agency has tested nearly 50 models over the past decade, very few of which have resulted in higher quality or better cost savings.[6]

Temporary Pause

Early in his term, President Biden announced that Elizabeth Fowler, an Obama administration alumna who helped draft and implement the ACA, would be the new director of CMMI.[7] One week later, on March 10, 2021, the administration paused a number of CMMI value-based models, including the Geographic Direct Contracting Model, Primary Care First Model's Seriously Ill Population option and the Kidney Care Choices Model, to "review model details."[8]

The effect of this "review" (the length of which review was not disclosed) was to delay the timelines for these models, by pushing back the participation application deadlines and performance periods.[8] While this decision was not necessarily indicative of plans to eliminate the models, it certainly did not instill confidence that value-based reimbursement was a priority for the administration. As one commentator noted, "It's natural for the administration to want to take a close look at the programs that are on the verge of being implemented to satisfy for themselves that this is not a disaster in the making where they'll be left holding the bag for something they did not conceptualize nor approve on their own."[8]

A "SIGNAL THAT CMMI AIMS TO ... CRACK DOWN ON INAPPROPRIATE CODING, SHIFT THE FOCUS OF VALUE-BASED PROGRAMS TO REDUCE PATIENT INEQUITIES, AND CUT DOWN ON INITIATIVES THAT ONLY SERVE TO EMPOWER DOMINANT PROVIDERS."

Subsequently, Fowler confirmed that the pause or termination of some CMMI models was not due to a change in course, stating, "I understand that collectively these announcements may have raised questions about where the center is headed next. …True innovation means failing until we get things right."[6]

In reviewing those models, CMMI was supposedly revamping the agency's strategy and thinking more creatively about how the models would work in tandem going forward, perhaps in response to the Medicare Payment Advisory Commission's (MedPAC's) October 2020 recommendation that CMMI "condense the sheer number of models" and reimagine the program.[6,9]

The focus of CMMI's review became clearer recently due to statements by CMMI leaders at various health care industry conferences. On September 30, 2021, CMMI's chief operating

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officer stated at the National Association of Accountable Care Organizations conference that he did not "think that [the Centers for Medicare & Medicaid Services (CMS)] will be promoting models that have more risk just for the sake of having more risk."[10]

New Strategic Direction

Health care industry commentators have interpreted this statement as a "signal that CMMI aims to restructure payment models to crack down on inappropriate coding, shift the focus of value-based programs to reduce patient inequities and cut down on initiatives that only serve to empower dominant providers with large market share."[10] This is a shift from the previous administration, which prioritized financial risk in their models, resulting in many health care providers choosing not to participate.[10]

On October 20, 2021, CMMI's chief strategy officer indicated at the Better Medicare Alliance conference that the Biden administration wants to "accelerate" the shift to value-based reimbursement by increasing participation (specifically in ACOs), stating, "We need to recognize we need to increase the number of ACOs and the beneficiaries assigned to them, increase opportunities for providers who want to participate, and deliver whole-person, integrated care."[11]

CMS AIMS TO MOVE ALL MEDICARE PART A AND B BENEFICIARIES ... TO A "CARE RELATIONSHIP WITH ACCOUNTABILITY FOR QUALITY AND TOTAL COST OF CARE BY 2030."

On the same day as the speech at the Better Medicare Alliance conference, CMS published a white paper describing CMMI's vision for the next 10 years.[12] The white paper listed five strategic objectives in implementing its vision of "a health system that achieves equitable outcomes through high quality, affordable, person-centered care:"

1. Drive accountable care: "Increase the number of beneficiaries in a care relationship with accountability for quality and total cost of care."
2. Advance health equity: "Embed health equity in every aspect of CMS Innovation Center models and increase focus on underserved populations."
3. Support innovation:"Leverage a range of supports that enable integrated, person-centered care—such as actionable, practice-specific data, technology, dissemination of best practices, peer-to-peer learning collaboratives, and payment flexibilities."
4. Address affordability: "Pursue strategies to address health care prices, affordability, and reduce unnecessary or duplicative care."
5. Partner to achieve system transformation: "Align priorities and policies across CMS and aggressively engage payers, purchasers[,] states, and beneficiaries to improve quality, to achieve equitable outcomes, to reduce health care costs.[12]

For each of the strategic objectives, CMS also listed certain measures of progress, meant to quantify advancement toward a given objective. Notably, pursuant to the achievement of the "drive accountable care" objective, CMS aims to move all Medicare Part A and B beneficiaries, and a vast majority of Medicaid beneficiaries, to a "care relationship with accountability for quality and total cost of care by 2030."[3]

As of 2020, 67% of Medicare Part A and B beneficiaries were in Medicare Advantage plans or attributed to an ACO; this means that approximately 30 million additional beneficiaries would need be attributed to an ACO or other VBR model over the next 10 years.[3] Whether or not CMS and CMMI's new strategies can achieve this lofty goal remains to be seen.

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HOLIDAY SHARING CARD

Supports AMA, MSMA Foundations

Thank You Holiday Sharing Card Contributors

The following SLMMS and Alliance members and friends contributed to the 2021 Holiday Sharing Card with donations to the American Medical Association Foundation and the Missouri State Medical Foundation.

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- Mrs. Angela Zylka

NORTH CENTRAL REGIONAL MEETING

The SLMMS Alliance partnered with the MSMA Alliance to host the North Central Regional Meeting at St. Louis Union Station Oct. 9-10. Alliance leaders from all over the country participated including AMA Alliance President Heather Rifkin from Mississippi. At the Saturday evening dinner, the guest speaker was David Barbe, MD, of Mountain Grove, Mo., current World Medical Association president and past AMA president. He was introduced by MSMA President Alex Hover, MD. Special thanks to Sue Ann Greco of the SLMMS Alliance and past AMA Alliance president, who co-chaired the event with Barbara Hover, MSMA Alliance president.

Pictured from left, Jo-Ellyn Ryall, MD; Gill Waltman; David Barbe, MD; Heather Rifkin; Barbara Hover; Alex Hover, MD; Sue Ann Greco; Angela Zylka.

Matthias "Matt" H. Backer, Jr., MD

Matthias "Matt" H. Backer, Jr., MD, retired U.S. Navy rear admiral, an ob-gyn, passed away on September 11, 2021, at the age of 94.

Born in St. Louis, Dr. Backer earned undergraduate degrees from Saint Louis University and the University of Colorado, and his medical degree from Saint Louis University School of Medicine. He completed an internship at the National Naval Medical Center in Bethesda, Md., and his residency in obstetrics and gynecology at Saint Louis University Hospital.

Dr. Backer gave more than 33 years of service to the Navy, including director and deputy surgeon general of Navy Reserve facilities, retiring as rear admiral in 1984. For many years, he shuttled between St. Louis and San Diego, working in both locations. He was a professor and former chair of the department of obstetrics and gynecology at Saint Louis University School of Medicine, and served as president of the medical staff at the former St. Anthony's Hospital, and chief of ob-gyn at the former St. Joseph's Hospital of Kirkwood. He retired from private practice in 1991. In 2003, SLMMS honored Dr. Backer with the Robert E. Schlueter Leadership Award, the Medical Society's highest honor. Dr. Backer joined the St. Louis Metropolitan Medical Society in 1954.

Dr. Backer was predeceased by his first wife, Laverne Knapp Backer, daughter Marilyn Parker and son Donald Backer. SLMMS extends its condolences to his second wife Georgia Garrison Backer; his children Mary Kathryn Backer, Matthias H. Backer III, Mary Louise Barrett, Robert Backer MD, Edward Backer, Mary Susan Conklin, Mary Carol Miller, Mary Patrice Banton, Joseph Backer, Brian Backer and Denis Backer; his 30 grandchildren; and his 18 great-grandchildren.

New Protocol … *continued from page 15*

References

1. The term "person" means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private. See 42 C.F.R. § 1003.110.
2. https://forms.oig.hhs.gov/forms/Self-Disc-Form-Protocol.aspx
3. 42 C.F.R. Part 1003.
4. Section 1128B(b).
5. The process for OIG advisory opinions is described at https://oig.hhs.gov/compliance/advisory-opinions/index.asp
6. Section 1877 of the Act.
7. Stark-only should be disclosed to CMS through its Self-Referral Disclosure Protocol (SDRP) found at: http://www.cms.gov/PhysicianSelfReferral/
8. https://oig.hhs.gov/compliance/self-disclosure-info/grant.asp or https://oig.hhs.gov/compliance/self-disclosure-info/contractor.asp
9. https://oig.hhs.gov/compliance/self-disclosure-info/provider-self-disclosure-protocol/.
10. The LEIE is available on-line at: https://exclusions.oig.hhs.gov

John J. Kelly, MD

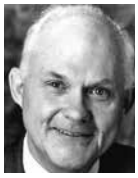
John J. Kelly, MD, a gastroenterologist, died September 28, 2021, at the age of 83.

Born in St. Louis, Dr. Kelly received his undergraduate degree from Rockhurst College and his medical degree from Saint Louis University. After completing his internship at Saint Louis University Hospital, he continued his training in residency at the Veterans Administration Hospital in St. Louis and the University of Minnesota Hospitals. He completed a fellowship in gastroenterology at Washington University School of Medicine.

Dr. Kelly served as a captain in the U.S. Air Force from 1966-1968. He was in private practice for more than 40 years, serving on the staffs of Barnes-Jewish Hospital, Missouri Baptist Medical Center, and St. Luke's Hospital. He was a co-founder of the Regional Endoscopy Society. Dr. Kelly joined the St. Louis Metropolitan Medical Society in 1971.

SLMMS extends its condolences to his wife Amelia "Amy" Kelly; his children Michael Kelly and Catherine Conner; and his three grandchildren.

Henry D. Onken, MD



Henry D. "Hank" Onken, MD, a plastic and reconstructive surgeon, died November 1, 2021, at the age of 89.

Born in St. Louis, Dr. Onken earned his undergraduate degree from Princeton University, and his medical degree from Harvard Medical School. He completed both his internship and residency, as well as advanced training in plastic surgery at Barnes Hospital and Washington University School of Medicine.

He served two years in the U.S. Army from 1962-1964 before returning to St. Louis to complete his medical training. His long career in private practice included serving on staff at multiple area hospitals. Dr. Onken was also an accomplished musician, playing clarinet in a local ensemble, and was involved with the Little Symphony and the St. Louis Christmas Carols Association. Dr. Onken joined the St. Louis Metropolitan Medical Society in 1966.

Dr. Onken was predeceased by his wife Deborah Smith Onken; SLMMS extends its condolences to his children John Onken, Michael Onken and Katie Onken; and his six grandchildren.

Proposed Rule on Surprise Billing Opposed by Physicians, Members of Congress

Members of Congress, the AMA and other organizations are joining forces to oppose regulations proposed by the Biden administration for implementation of the 2020 No Surprises Act intended to end the practice of surprise billing.

At issue is the dispute resolution process as presented in the Sept. 30 Interim Final Rule implementing the No Surprises Act. The proposed rule calls for the median in-network rate to be the default consideration during the Independent Dispute Resolution (IDR) process provided for in the law. Opponents believe the proposed rule sets a "default" or "benchmark" rate in violation of the statutory intent of the law—which was for an open negotiation process followed by arbitration if needed. As a result, the proposed rule favors insurance companies.

"Congress rejected a benchmark rate and determined the best path forward for patients was to authorize an open negotiation period coupled with a balanced IDR process."

The AMA and 100 other medical associations including the Missouri State Medical Association on Nov. 17 sent a letter to the departments of Health and Human Services, Labor and Treasury asking that the rule be modified. The letter said in part:

"We ask that you revise the most recent Interim Final Rule to conform with the No Surprises Act's statutory language to allow an IDR entity the discretion to consider all the relevant information submitted by the parties to determine a fair out-of-network payment to physicians, without creating a rebuttable presumption that directs an IDR entity to consider the offer closest to the (median in-network rate) as the appropriate payment amount."

In a Nov. 5 joint letter, over 150 U.S. representatives objected to the proposed rule:

"Following a comprehensive process that included hearings, markups and extensive negotiations, Congress rejected a benchmark rate and determined the best path forward for patients was to authorize an open negotiation period coupled with a balanced IDR process. … Unfortunately, the parameters of the IDR process in the Interim Final Rule released on Sept. 30 do not reflect the way the law was written, do not reflect a policy that could have passed Congress, and do not create a balanced process to settle payment disputes."

On Nov. 22, Health and Human Services secretary Xavier Becerra defended the proposed regulations, accusing some physicians and hospitals of overcharging patients.

"Despite some state efforts to tackle surprise medical bills, patients continue to experience exorbitant medical expenses due to lack of transparency and rules. The Biden-Harris administration will continue implementing federal regulations from the No Surprises Act to not only protect the patients but also curb rising costs in health care," Becerra said in an HHS news release.

A report released by HHS on Nov. 22 found that surprise medical bills are relatively common among privately-insured patients and can average more than $1,200 for services provided by anesthesiologists, $2,600 for surgical assistants, and $750 for childbirth-related care.

The Interim Final Rule was published Oct. 7, giving stakeholders 60 days to comment and seek changes. The law and regulations would take effect Jan. 1. Becerra told Kaiser Health News that the department would consider making changes if needed. The HHS report also noted that the law requires extensive monthly and annual reporting to regulators and Congress to monitor the implementation.

Read the full AMA letter at https://bit.ly/AMA-NSA-2021

COVID-19 Vaccine: Now Is the Time

Resources for Physician-Patient Education

Attention physicians:
Please encourage your patients to get the COVID-19 vaccine.

Why get the vaccine?

It's safe.

Over 450 million vaccine doses have been administered in the U.S. to date.

Protect your family.

Avoid infecting family members, especially those with health risks.

Protect yourself.

Don't risk serious illness.

Protect the community.

The sooner most of us get immunized, the sooner that life can return to normal.

Where can I get the vaccine?

Hospital Systems

- BJC HealthCare – https://www.bjc.org/Coronavirus/Covid-19-Vaccines
- Mercy – https://www.mercy.net/forms/vaccinations/
- SSM Health – https://webforms.ssmhealth.com/covidvaccine
- St. Luke's Hospital – https://lukesvaccine.com/

Health Departments

- St. Louis County – https://stlcorona.com/covid19-vaccines/ or 314-615-2660
- City of St. Louis – http://bit.ly/stl-vacc or 314-612-5100
- St. Charles County – http://bit.ly/scc-vacc or 636-949-1899
- Jefferson County – https://www.jeffcohealth.org/covid19-vaccine or 636-797-3737

Pharmacies and Retail

- CVS – https://www.cvs.com/immunizations/covid-19-vaccine
- Walmart – http://bit.ly/wm-vacc
- Missouri Pharmacy Program (independent pharmacies) – http://bit.ly/mopharm
- Walgreens – https://www.walgreens.com/findcare/vaccination/covid-19

State of Missouri Vaccination Events

- https://covidvaccine.mo.gov/navigator/ or 877-435-8411

ST. LOUIS METROPOLITAN MEDICAL SOCIETY

IS YOUR MONEY WORKING AS HARD AS YOU ARE?

A LOWER FEE COULD HAVE PUT AN EXTRA $152,658 IN YOUR POCKET.

	1.00% Management Fee	0.50% Management Fee
12/31/10	$1,000,000	$1,000,000
12/31/20	$3,359,867*	$3,512,525*

At Triad Financial Group, we're pleased to offer SLMMS members a reduced annual portfolio management fee of 0.5%. That's half the rate typically charged by financial advisors,** and the difference in costs or fees can really add up. **So why pay more?**

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* Based on a hypothetical $1 million invested in positions held on in the S&P 500 Index. Over a 10-year period ending 12/31/2020, returns would have been $152,658 higher with a 0.5% annual portfolio management fee versus a 1% fee. Past performance is not indicative of future returns.

** "Typical rate charged by financial advisors" claim is based on a 2016 *InvestmentNews* study (http://blog.runnymede.com/how-much-to-pay-a-fee-only-advisor-a-look-at-average-annual-fees) showing an average advisor fee of 1.01% for an account valued at between $1 million and $5 million. Rates charged by financial advisors vary. Other fees and transaction costs apply. Similar services may be available from other investment advisers at a lower cost.

All indices are unmanaged and investors cannot actually invest directly into an index. Unlike investments, indices do not incur management fees, charges, or expenses.

This is a hypothetical example and is for illustrative purposes only. No specific investments were used in this example. Actual results will vary.