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COVID-19 treatments: What's FDA authorized, and what works

By: Andis Robeznieks, Senior AMA News Writer

New cases of COVID-19 infections are surging in the U.S. and are at the highest levels of the pandemic. The fast-spreading variant, B.1.1.529, more widely known as Omicron, is fueling this acceleration, according to the Centers for Disease Control and Prevention (CDC).

The agency recommends vaccines and booster shots as the best preventive measures against severe illness, hospitalizations and death. But, in a **health advisory** issued by the CDC Health Alert Network, it notes that there are therapeutics available for preventing and treating COVID-19 in specific at-risk populations—such as patients with cancer, chronic kidney disease, obesity, chronic obstructive pulmonary disease or diabetes.

The advisory also notes, however, that these medications differ in efficacy, route of administration, risk profile, Food and Drug Administration (FDA) authorization status and availability.

The advisory is intended to help familiarize physicians and other clinicians with what therapeutics are available, understand how and when to prescribe them, recognize contraindications, and how to prioritize their use when faced with supply constraints.

These therapeutics include monoclonal antibodies, antivirals and pre-exposure prophylaxis products. The advisory details their effectiveness and also provides strategies for high-risk groups.

In its "**Omicron Variant: What you need to know**" document, the CDC said it "expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms."

More than 832,000 people in the U.S. have died from COVID-19, with the first death caused by the Omicron variant recorded in the Houston area Dec. 20.

The CDC health advisory notes that the Omicron variant "is not neutralized" by the commonly prescribed monoclonal antibody-based COVID-19 treatments bamlanivimab, etesevimab, casirivimab or imdevimab.

Sotrovimab has been shown to be effective against all COVID-19 variants including Omicron, but there are limited supplies of this monoclonal antibody medication and there has been "some reduction in neutralization concentration," the advisory says.

The FDA issued an emergency use authorization for sotrovimab for mild-to-moderate COVID-19 in patients older than 12 and weighing at least 40 kilograms who are at high risk for progression to severe illness. It is not authorized for patients already hospitalized for COVID-19 or who require oxygen because of COVID-19.

Early studies found that remdesivir, an antiviral drug first used to treat Ebola, could reduce hospital stays for patients with COVID-19 if given within seven days of symptom onset. The advisory cites a more recent study, "Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients," published in *The New England Journal of Medicine*, which found that a three-day course of remdesivir resulted in an 87% lower risk of hospitalization or death compared with a placebo.

The advisory notes, however, that outpatient use of remdesivir requires the use of an intravenous infusion center with skilled staffing.

Two oral antivirals, paxlovid and molnupiravir, were made available for outpatients with mild to moderate COVID-19 under FDA emergency use authorization. Both drugs are taken twice daily for five days. Compared with placebo, paxlovid is more effective against hospitalization and death, 88%, than molnupiravir, 33%, but it is in short supply. Treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy.

President Joe Biden announced that the U.S. government has committed to buy a total of at least 20 million courses of paxlovid from Pfizer. Given the existing shortage, however, the CDC advisory recommends the treatment be prioritized for high-risk populations.

Both also carry risks. Paxlovid has a potential for a severe interaction with ritonavir, which is used for HIV treatment. Molnupiravir is not recommended for patients who are pregnant or breastfeeding.

Evusheld is the only product to receive FDA emergency use authorization for pre-exposure prophylaxis for COVID-19.

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It includes two long-acting anti-SARS-CoV-2 monoclonal antibodies and is intended for the "highest risk immunocompromised patients" for whom vaccination is not expected to be effective. It is not intended as a treatment.

The advisory highlights the need for virus-specific diagnostic testing by noting that two pairs of monoclonal antibody treatments bamlanivimab and etesevimab and casirivimab and imdevimab received emergency use authorization for the Delta variant, but are considered ineffective against Omicron.

The advisory also recommends encouraging patients to keep appointments for routine care and adhere to treatment regimens. ✦

MDHHS NEWS

State of Michigan Receives Initial Limited Supply of New Oral COVID-19 Medications

MDHHS issues eligibility criteria and prescribing requirements to reach those most at-risk; continues to urge vaccination and boosters

In January Michigan received its first shipment of new oral medications to treat COVID-19, paxlovid and molnupiravir, following the recent emergency use authorization by the FDA.

These antivirals are designed for the outpatient treatment of mild to moderate COVID-19. Both medications may only be prescribed for a patient by physicians, advanced practice registered nurses and physician assistants.

When administered to non-hospitalized patients within five days of symptom onset, these antivirals may reduce symptoms and the risk of hospitalizations and emergency room visits associated with the virus.

Due to the limited quantity of these drugs, the Michigan Department of Health and Human Services (MDHHS) has developed eligibility criteria and prescribing requirements for the antivirals.

"The authorization of these new medications provides another important tool to help fight the virus," said Elizabeth Hertel, MDHHS director. "Due to limited availability of these antivirals, health care providers will need to determine the best course of treatment for their patients based on eligibility criteria. We ask Michiganders to be patient as providers will prioritize people at highest risk for developing serious illness from the virus. We are committed to distributing these pills equitably across the state, and access will increase as Michigan receives more allocations from the federal government."

Priority Eligibility Criteria for therapeutics, including antiviral medication and monoclonal antibody therapy (mAb), **will remain in effect until supply is able to meet demand and will be periodically reviewed as appropriate.**

MDHHS continues to strongly recommend getting vaccinated and boosted for the best protection against the virus.

"It's important to remember these drugs are not a substitution for protecting yourself by getting vaccinated and wearing a mask in public places," said Dr. Natasha Bagdasarian, MDHHS chief medical executive. "Getting vaccinated continues to be the best protection against severe illness and hospitalization, and we urge all Michiganders over age 5 to get vaccinated as soon as possible. Continue to wear well-fitting masks over your nose and mouth, test and social distance to prevent the spread of COVID-19, avoid large gatherings and get vaccinated and boosted if you haven't already."

Treatment with mAb continues to be an important therapy for mild to moderate COVID-19 infection and is preferred over treatment with molnupiravir whenever it can be readily accessed. Based on current evidence, mAb therapy is also a comparable alternative to paxlovid for patients who do not have access to the oral medication, have contraindications to the medication (e.g., pregnancy), or are beyond five days (but within 10 days) of symptom onset. Treatment with mAb should be considered for patients who are in eligible lower risk tiers in the Priority Eligibility Criteria.

Paxlovid is indicated for the treatment of mild-to-moderate COVID-19 in patients 12 years of age and older who are at high risk for progression to severe COVID-19, including hospitalization or death, and who meet the current Priority Eligibility Criteria.

Paxlovid currently has limited availability through the following sites:

- Selected Federally Qualified Health Centers and Tribal Health Centers.
- Selected Meijer Pharmacies in southeast and east central Michigan.

thank you
for Your Generosity!

2021 MCMS Foundation Holiday Sharing Card Project Raised $7,252

We would like to thank the Macomb County Medical Society members who participated in this year's Holiday Sharing Card Project. Your generous donations enabled us to raise $3,781 for the Macomb County Food Program which feeds hungry families throughout Macomb County and $3,471 for Turning Point Shelter for women which assists victims/survivors of domestic violence and sexual assault.

Molnupiravir is indicated for the treatment of mild-to-moderate COVID-19 in adults ages 18 and older who are at high risk for progression to severe COVID-19, including hospitalization or death, and only when alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate and who meet the current Priority Eligibility Criteria.

Molnupiravir currently has limited availability through the following sites:

- All Meijer Pharmacies (based on supply).
- Selected retail pharmacies in areas not served by Meijer (based on supply).

Additional information on oral antiviral medications and monoclonal antibody therapy, including priority eligibility criteria based on MDHHS scarce resource allocation principles is available at **www.Michigan.gov/COVIDTherapy**.
Michigan residents seeking more information about the COVID-19 vaccine can visit **www.Michigan.gov/COVIDvaccine**.

CDC J&J Vaccine Clinical Guidelines Reminder

As a reminder, CDC has endorsed recommendations made by the Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19, expressing a clinical preference for individuals to receive an mRNA COVID-19 vaccine over J&J's COVID-19 vaccine. ACIP's unanimous recommendation followed a robust discussion of the latest evidence on vaccine effectiveness, vaccine safety and rare adverse events, and consideration of the U.S. vaccine supply. This updated CDC recommendation follows similar recommendations from other countries, including Canada and the United Kingdom. Given the current state of the pandemic both here and around the world, the ACIP reaffirmed that receiving any vaccine is better than being unvaccinated. Individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to J&J's COVID-19 vaccine.

MDHHS supports this CDC recommendation for a clinical preference for individuals to receive an mRNA COVID-19 vaccine over J&J's COVID-19 vaccine. It is permissible to use J&J COVID-19 vaccine in certain scenarios such as:

- An individual requests the use of J&J vaccine.
- An individual is otherwise unable or unwilling to receive an mRNA vaccine.
  - o An individual may be unable to receive an mRNA vaccine if they have had a severe allergic reaction to any ingredient in an mRNA vaccine or if they had a severe allergic reaction after receiving a dose of an mRNA COVID-19 vaccine.
- An individual needs a one-dose vaccine to comply with travel requirements, work vaccine mandates, etc.

Please keep in mind that any individual receiving a J&J vaccine must be informed of the risks and benefits prior to vaccination.

J&J ORDERING

Given the large amount of J&J vaccine inventory available, MDHHS is encouraging providers to utilize on-hand doses of J&J rather than placing a new MCIR E-Order. Providers should still follow the clinical preference guidelines for an mRNA vaccine, but if J&J vaccine is needed, on-hand doses should be utilized first. Continue to check your inventory and expiration dates using first-in/first-out storage and handling practices. To request doses for redistribution, providers should contact their local health department (**LHD**) regarding available vaccine.

If necessary, an E-Order in MCIR may be placed if the following applies:

- Provider is confident in utilizing the minimum order quantity (100 doses)

AND

- Provider has contacted the local health department and is unable to receive redistributed doses from the local health department or another provider.

LHDs, please work with your MDHHS Field Representative prior to order approval to discuss ordering versus redistribution and to assure inventories are continuing to be assessed.

As a reminder, E-Orders are not automatically approved. They are sent to the LHD for review and approval before being processed by MDHHS.

REMINDER: Please remember to include ancillary supplies during redistribution. CDC's redistribution tool for ancillary supplies can assist. Utilize this tool to help ensure all the syringes, needles, supplies, and diluent needed for vaccine administration move with vaccine during redistribution.

If you have questions, please contact **checcimms@michigan.gov**. ✦

Apple Watch Study Provides an Unprecedented Look at the Health Status of A Diverse Patient Population

By: Kelly Malcom
Photo Credit: Joe Hallisy, Michigan Medicine

Participants from the University of Michigan Health-led study range in age, race and health conditions.

Researchers in the health and wellness space have typically relied on people to report their personal health data, like activity levels, heart rate or blood pressure, during brief snapshots in time.

Wearable health devices, such as the popular Apple Watch, have changed the game, surfacing meaningful data that can paint a more complete picture of daily life and resulting health and disease for clinicians.

Early results from a landmark, three-year observational study called MIPACT, short for Michigan Predictive Activity & Clinical Trajectories, provide insight into the baseline health status of a representative group of thousands of people, as reported in a paper published in *The Lancet Digital Health*.

"From both a research and clinical standpoint, as we design digital health interventions or make recommendations for our patients, it's important to understand patients' baseline activity levels," said Jessica Golbus, MD, of University of Michigan Health's Division of Cardiovascular Medicine, and co-investigator on the study.

The University of Michigan Health study is led by Sachin Khetarpal MD, the associate dean for Research Information Technology and professor of Anesthesiology and launched in 2018 as a collaboration with Apple. The study aims to enroll a diverse set of participants across a range of ages, races, ethnicities and underlying health conditions.

Golbus notes that one of the biggest successes of the study so far was their ability to recruit from groups that have largely been underrepresented or unrepresented in digital health research. For example, 18% of the more than 6,700 participants were 65 or older, 17% were Black, and 17% were Asian.

Ten percent of participants had diabetes and a third had hypertension. More than a quarter of participants reported depression. **Summary data from the MIPACT study across participants is available in a web-based research tool that was developed by the study investigators.**

"With this tool, researchers and participants can choose certain clinical and demographic criteria—age, body mass index, sex—and see not only how many participants fall into that cohort but their average resting heart rate, blood pressure, and other activity data," said Nicole Eyrich, clinical research project manager for the study. "It provides more context in the form of normative data for researchers."

The data is a potential game-changer for clinicians.

"As a cardiologist who takes care of patients dealing with heart failure, it's important that more than 200 patients in our study have heart failure. Understanding what their baseline information looks like is going to be really informative and allow us to start with more accurate estimates of patients' activity levels in daily life," Golbus said.

The paper examines the first 90 days of the study, describing heart rate and activity data collected with the Apple Watch or iPhone and blood pressure measurements collected with the Omron wireless blood pressure cuff.

Participants wore their Apple Watch on almost 90 percent of the study days for an average of 15.5 hours a day. Overall, more than 200 million heart rate measurements were collected with Apple Watch and 1.1 million blood pressure readings with the Omron blood pressure cuff.

Participants 65 and older had significantly lower resting and walking heart rates, and women had resting heart rates on average 3 beats per minute higher than men. When stratified by self-declared race, Black participants had the highest heart rates and white participants the lowest. Activity levels also varied by race and ethnicity and by the presence of certain clinical conditions. Together, these differences demonstrate that patient-specific context is an important consideration when clinicians interpret wearable and home blood pressure data.

From a technology standpoint, the study also revealed a significant discrepancy in activity levels as measured by the watch and phone, with the latter underestimating step counts.

Said Golbus, "I think what this means is that not all mobile device signals are created equal and that, in the future, interpretation of these signals will require knowledge of the device from which these signals were collected."
Golbus adds that the ultimate results of the study will be important clinically for physicians.

"Pretty frequently, I get asked by my patients what their wearable device data means, and it's really challenging to understand its implications for their long-term health," said Golbus. She notes that the three-year follow-up period will be most informative as they seek to contextualize the data signals from the Apple Watch with information from participants' electronic medical records and survey data.

The data may also provide the unexpected ability to examine the effects of the COVID-19 pandemic. Said Golbus, "We have data on participants both before and after the onset of the pandemic, so we really have the capability to evaluate how physiologic parameters changed over the course of the pandemic both as a result of illness but also due the global impact the pandemic has had on all of our lifestyles."

About MIPACT
MIPACT is built upon experience gained from the enrollment of 60,000 participants over the last six years of the Michigan Genomics Initiative, part of Precision Health at the University of Michigan, as well as the infrastructure of the Michigan Institute for Clinical & Health Research.

Find more information on MIPACT.

Paper cited: "Wearable device signals and home blood pressure data across age, sex, race, ethnicity, and clinical phenotypes in the Michigan Predictive Activity & Clinical Trajectories in Health (MIPACT) study: a prospective, community-based observational study," *The Lancet Digital Health*. **DOI: 10.1016/S2589-7500(21)00138-2**

This article was originally posted on the Michigan Medicine News website. ✦

IN MEMORIAM

Scot F. Goldberg, MD, MBA

June 17, 1960 – December 21, 2021

Farmington Hills, MI

It is with heavy hearts that we announce the passing of Scot F. Goldberg, MD, 61, on December 21, 2021. He was predeceased by his parents, Jacob and Joyce Goldberg, and his parents-in-law Zvi and Betty Wegener. He is survived by his beloved wife Judith and his cherished children Jessica and Ryan.

Dr. Goldberg was born June 17, 1960 in Queens, New York. He graduated from the Massachusetts Institute of Technology with a Bachelor of Science in 1982. He earned his Medical Degree from the Wayne State University School of Medicine in 1986 and did his internship and residency at Beaumont Royal Oak Hospital. Dr. Goldberg received his Master of Science in Business Administration from Madonna University in 1998. Dr. Goldberg practiced as a Board Certified Internal Medicine specialist in Warren from 1989 until his sudden passing in 2021.

Dr. Goldberg joined the Macomb County Medical Society (MCMS) and the Michigan State Medical Society (MSMS) in 1989. Over the years he served on several committees both at the county and state level. Dr. Goldberg was a member of the Macomb County Medical Society Board of Directors from 1998-2015 and served as President of the Society in 2001. He also served on the MSMS Board of Directors from 2006-2015 and the MI Doctors' Political Action Committee Board of Directors from 2002-2021.

The Funeral was held at Ira Kaufman Chapel in Southfield on December 28, 2021.

We would like to welcome the following New Members

Usman Ashraf, MD
Physical Medicine & Rehabilitation
Medical School: University of Toledo College of Medicine (OH), 2017. Post Graduate Education: Beaumont Hospital – Taylor, completed in 2021. Hospital Affiliations: Ascension Macomb Oakland. Currently practicing at Center for Physical Medicine & Rehabilitation, 13850 E. 12 Mile Rd., Warren, MI 48088, p. 586-552-4499, www.physicalmedicinerehab.com.

Heather H. Orkwis, DO
Dermatology – Board Certified
Medical School: Philadelphia College of Osteopathic Medicine, 2009. Post Graduate Education: Lankenau Hospital (PA), completed in 2010; St. Joseph's Mercy Ann Arbor, completed in 2013. Hospital Affiliations: Troy Beaumont, McLaren Macomb. Currently practicing at Midwest Center for Dermatology & Cosmetic Surgery, 43900 Garfield Rd., Ste. 100, Clinton Twp., MI 48038, p. 586-286-0112, www.mwdermatology.com.

Tina Gay Louise Pickett-Baisden, MD
Dermatology – Board Certified
Medical School: Wayne State University School of Medicine. Post Graduate Education: Henry Ford Hospital, Detroit; University of Michigan, Ann Arbor. Hospital Affiliations: Ascension Macomb Oakland. Currently practicing at Iacobelli & DiGregorio, PC, 16510 19 Mile Rd., Clinton Twp., MI 48038, p. 586-263-7200, www.mwdermatology.com.

Karolina Skrzypek, MD
Internal Medicine – Board Certified
Medical School: Jagiellonian University Medical College (Poland), 2011. Post Graduate Education: Henry Ford Hospital, completed in 2014. Hospital Affiliations: University of MI Medical Center.

Brian M. Stewart, DO
Dermatology – Board Certified
Medical School: Western University of Health Science College of Osteopathic Medicine of the Pacific (CA), 2005. Post Graduate Education: Detroit Medical Center, completed in 2006; St. Joseph's Mercy Ann Arbor, completed in 2009. Hospital Affiliations: Troy Beaumont, McLaren Macomb. Currently practicing at Midwest Center for Dermatology & Cosmetic Surgery, 43900 Garfield Rd., Ste. 100, Clinton Twp., MI 48038, p. 586-286-0112, www.mwdermatology.com.

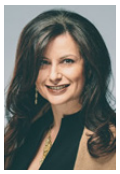
SHARE YOUR NEWSWORTHY ITEMS!

Have you or a MCMS colleague been elected to a position *(specialty society, hospital, community based program, etc.)* or honored for your volunteer service within the community or abroad? Let us know.

We would like to recognize MCMS members in the *"Member News"* section of the Medicus. Contact Heidi Leach at macombcms@gmail.com with newsworthy information.

Publication is subject to availability of space and the discretion of the Editor.

Daniel M. Stewart, DO
Dermatology – Board Certified
Medical School: Kansas City University of Medicine College of Osteopathic Medicine, 1970. Post Graduate Education: Mt. Clemens General Hospital, completed in 1971; Detroit Medical Center, completed in 1975. Hospital Affiliations: Troy Beaumont, McLaren Macomb, St. Joseph's Mercy Ann Arbor. Currently practicing at Midwest Center for Dermatology & Cosmetic Surgery, 43900 Garfield Rd., Ste. 100, Clinton Twp., MI 48038, p. 586-286-0112, www.mwdermatology.com.



Mary G. Veremis-Ley, DO
Dermatology – Board Certified
Medical School: Michigan State University College of Osteopathic Medicine, 2001. Post Graduate Education: Pontiac Osteopathic Hospital, completed in 2002; Case Western Reserve University/University Hospitals of Cleveland, completed in 2005. Hospital Affiliations: Troy Beaumont, McLaren Macomb, Ascension Macomb Oakland, St. Joseph's Mercy Ann Arbor. Currently practicing at Midwest Center for Dermatology & Cosmetic Surgery, 43900 Garfield Rd., Ste. 100, Clinton Twp., MI 48038, p. 586-286-0112, www.mwdermatology.com.

We would like to welcome the following New Members from the Greater Macomb Physician Network

Kenneth K. Andrews, MD
Psychiatry – Board Certified
Medical School: Wayne State University, 1983. Post Graduate Education: Sinai Grace Hospital, Psychiatry, completed in 1984; Detroit Medical Center completed in 1987. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Henry Ford Macomb Behavioral Medicine, 215 North Ave., Mt. Clemens, MI 48043, p. 586-466-9445.

Basivi R. Baddigam, MD
Psychiatry – Board Certified
Medical School: Guntur Medical College (India), 1978. Post Graduate Education: Wayne State University, completed in 1991; Boston University Medical Center, completed in 1988; Michigan State University, completed in 1993. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Baddigams Clinic, 43211 Dalcoma Dr., Ste. 3, Clinton Twp., MI 48038, p. 586-466-9445.

Prameela Baddigam, MD
Psychiatry – Board Certified, Addiction Medicine – Board Certified, Geriatric Psychiatry – Board Certified
Medical School: Guntur Medical College (India), 1984. Post Graduate Education: Government Medical College (India), completed in 1984; Wayne State University, completed in 1993. Hospital Affiliations: Henry Ford Macomb, Henry Ford Kingswood. Currently practicing at Baddigams Clinic, 43211 Dalcoma Dr., Ste. 3, Clinton Twp., MI 48038, p. 586-263-6812.

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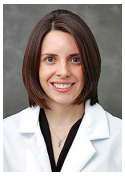
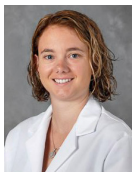
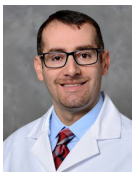


Lindsay M. Beros, MD
Obstetrics & Gynecology
Medical School: Tufts Medical Center (MA), 2003. Post Graduate Education: Beaumont Hospital - Royal Oak, completed in 2007. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 30795 23 Mile Rd., Ste. 208, Chesterfield, MI 48047, p. 586-421-3160.



Nicole E. Dolan, DO
Obstetrics & Gynecology – Board Certified
Medical School: Michigan State University College of Human Medicine, 2005. Post Graduate Education: Henry Ford Macomb Hospital, completed in 2009. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 16360 26 Mile Rd., Macomb, MI 48042, p. 586-336-2390.



Eddie F. El-Yussif, DO
Orthopedic Surgery – Board Certified
Medical School: Kansas City University, Medicine & Biosciences (MO), 2002. Post Graduate Education: Garden City Hospital, completed in 2008; Anderson Orthopaedic Research Institute (VA), completed in 2009. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb Orthopedics, 15520 19 Mile Rd., Ste. 430, Clinton Twp., MI 48038, p. 586-228-6200.

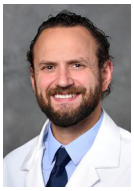
Steven J. Ferrucci, MD
Obstetrics & Gynecology
Medical School: University of Michigan, 1986. Post Graduate Education: Eastern Virginia Medical School (VA), completed in 1990. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 16151 19 Mile Rd., Ste. 300, Clinton Twp., MI 48038 p. 586-228-1760.

Valal K. George, MD
Urology – Board Certified
Medical School: Himachal Pradesh Medical College (India), 1973. Post Graduate Education: University of Kerala (India), completed in 1976; Safdarjung Hospital (India), completed in 1978; Rumailah/ Hamad Hospital (Qatar), completed in 1987; St. Peter's Hospital (UK), completed in 1988; Norfolk and Norwich Hospital (UK), completed in 1990; Wayne State University, completed in 1997; Wayne State University, completed in 2001. Hospital Affiliations: Henry Ford Macomb, McLaren Macomb, Ascension Macomb Oakland, Ascension St. John, Troy Beaumont. Currently practicing at MI Institute of Urology, 20952 12 Mile Rd., Ste. 200, St. Clair Shores, MI 48081, p. 586-771-4820, www.michiganurology.com.

Mohammad Ghaffarloo, MD
Internal Medicine
Medical School: Universidad Mundial Dominicana (Dominican Republic), 1985. Post Graduate Education: Georgetown University Hospital, completed in 1990; St. Joseph Mercy Ann Arbor, completed in 1992; Wayne State University, completed in 1994. Hospital Affiliations: Henry Ford Macomb, Ascension Macomb Oakland. Currently practicing at 15945 19 Mile Rd., Ste. 100, Clinton Twp., MI 48038, p. 586-286-8677.

Daniel L. Jensen, DO
Vascular Surgery – Board Certified
Medical School: Kansas City University College of Osteopathic Medicine (MO), 2000. Post Graduate Education: Mesa General Hospital Medical Ctr. (AZ), completed in 2001; Ascension Macomb Oakland Hospital, completed in 2005; Henry Ford Macomb Hospital, completed in 2007. Hospital Affiliations: Henry Ford Macomb, Ascension Macomb Oakland. Currently practicing at 3272 12 Mile Rd., Ste. 102, Warren, MI 48092, p. 586-754-2558.

Shabbir F. Khambati, MD
Ophthalmology
Medical School: Wayne State University School of Medicine, 1997. Post Graduate Education: Kresge Eye Institute, completed in 2001. Hospital Affiliations: McLaren Macomb. Currently practicing at Lake Lazer Eye Center, 35776 Harper Ave, Clinton Twp., MI 48035, p. 586-792-3891, www.useemore.com.



Michael R. Maceroni, DO
Orthopedic Surgery
Medical School: Michigan State University College of Osteopathic Medicine, 2014. Post Graduate Education: Henry Ford Wyandotte Hospital, completed in 2015; Henry Ford Macomb Hospital, completed in 2020. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb Orthopaedics, 43251 Commons Dr., Clinton Twp., MI 48038, p. 586-759-4700.

Benjamin S. Monson, DO
Ophthalmology – Board Certified
Medical School: Des Moines University-College of Osteopathic Medicine, 2010. Post Graduate Education: Ascension Macomb Oakland Hospital, completed in 2014. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Fite Eye Center, 16530 19 Mile Rd., Clinton Twp., MI 48038, p. 586-226-2020, www.fiteeyecenter.com.

MEDICAL RECORDS OF RETIRED PHYSICIANS

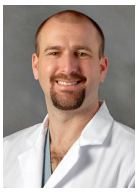
Patients looking for their medical records from retired physicians frequently contact the MCMS. If you are retired or will be retiring shortly, please contact the MCMS at 877-264-6592 or email macombcms@gmail.com and let us know how patients can retrieve their records. If the records have been destroyed, please inform us of that also so we can note our database accordingly. Thank you!

Vinay Pampati, DO
Orthopedic Surgery – Board Certified
Medical School: Michigan State University College of Osteopathic Medicine, 2004. Post Graduate Education: McLaren Oakland, completed in 2009; Los Angeles Orthopedic Institute (CA), completed in 2010. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Henry Ford Macomb Orthopedics, 15520 19 Mile Rd., Ste. 430, Clinton Twp., MI 48038, p. 586-228-6200.

Shivanhalli Prakash, MD
Surgery – Board Certified
Medical School: Bangalore Medical College (India), 1969. Post Graduate Education: Ascension Macomb Oakland Hospital, completed in 1989; Doctors' Hospital of Michigan/OPMC, completed in 1996. Hospital Affiliations: Henry Ford Macomb, Ascension Macomb Oakland, Ascension St. John. Currently practicing at 43311 Commons Dr., Clinton Twp., MI 48038, p. 586-263-8555.

Stephen F. Redding, MD
Obstetrics & Gynecology
Medical School: Wayne State University School of Medicine, 1987. Post Graduate Education: Ascension St. John Hospital, completed in 1991. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 17941 Hall Rd., Macomb, MI 48044, p. 586-465-4722.

Fremont L. Scott, DO
Orthopedic Surgery – Board Certified
Medical School: Michigan State University College of Osteopathic Medicine, 1980. Post Graduate Education: Henry Ford Macomb Hospital, completed in 1985. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Henry Ford Macomb Orthopedics, 43251 Commons Dr., Clinton Twp., MI 48038, p. 586-759-4700.



Kenneth A. Scott, DO
Orthopedic Surgery – Board Certified
Medical School: Philadelphia College of Osteopathic Medicine (PA), 1995. Post Graduate Education: Doctors Hospital (OH), completed in 1996; Henry Ford Macomb Hospital, completed in 2000. Hospital Affiliations: Henry Ford Macomb. Currently practicing at Henry Ford Macomb Orthopedics, 12150 30 Mile Rd., Ste. 105, Washington Twp., MI 48095, p. 586-336-7333.

Manaf Seid-Arabi, MD
Neurology, Sleep Medicine
Medical School: Tabriz University Of Medical Sciences (Iran), 1972. Post Graduate Education: Wayne State University, completed in 1980. Currently practicing at 15945 19 Mile Rd., Ste. 106, Clinton Twp., MI 48038, p. 586-263-0610, www.myndsdoctor.com

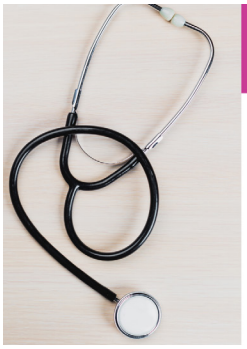
MEMBERSHIP REPORT

Dawn M. Severson, MD
Medical Oncology – Board Certified, Internal Medicine – Board Certified
Medical School: Wayne State University School of Medicine, 2001. Post Graduate Education: Beaumont Hospital - Royal Oak, completed in 2006. Hospital Affiliations: Henry Ford Macomb, McLaren Macomb, Henry Ford Detroit, Henry Ford W. Bloomfield. Currently practicing at Henry Ford Hematology Oncology, 43630 Hayes Rd., Ste. 200, Clinton Twp., MI 48038, p. 586-323-4530.

Laurie C. Stanczak, MD
Obstetrics & Gynecology – Board Certified
Medical School: Wayne State University School of Medicine, 1996. Post Graduate Education: Ascension St. John Hospital, completed in 2000. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 30795 23 Mile Rd., Ste. 208, Chesterfield, MI 48047, p. 586-421-3160.

Anil K. Thomas, MD
Pulmonary Disease – Board Certified, Internal Medicine – Board Certified
Medical School: Stanley Medical College University of Chennai (India), 1973. Post Graduate Education: Sinai Grace Hospital, completed in 1977; Detroit Medical Center/Sinai Grace Hospital, completed in 1979. Hospital Affiliations: Henry Ford Macomb. Currently practicing at 43171 Dalcoma Dr., Ste. 9, Clinton Twp., MI 48038, p. 586-263-0670.

Julie A. Thompson, DO
Obstetrics & Gynecology – Board Certified
Medical School: Michigan State University College of Osteopathic Medicine, 2011. Post Graduate Education: St. Joseph Mercy Oakland, completed in 2015. Hospital Affiliations: Henry Ford Macomb, Henry Ford Detroit. Currently practicing at Henry Ford Macomb OB-GYN, 14049 E. 13 Mile Rd., Ste. 6, Warren, MI 48088, p. 586-558-9966.



Ivermectin Rx for COVID-19: Insurance coverage doesn't match evidence

By: Kara Gavin

Study shows health plans paid most of the cost of ivermectin, despite drug's lack of effect on COVID-19.

Even though clinical trials haven't shown it works against COVID-19, doctors continue to prescribe ivermectin – and a new study suggests health insurers are heavily subsidizing the cost of those prescriptions.

The study's authors call for insurers to align their coverage of the drug with the level of medical evidence surrounding it — just like they do for other medications, tests and procedures.

The study, published in *JAMA* by a team from the University of Michigan and Boston University, uses insurance data to study how much health plans paid for oral ivermectin in late 2020 and early 2021. They found that plans paid 61% to 74% of the cost, or about $36 to $39 per prescription.

As a result of this coverage, the researchers estimate that United States private and Medicare plans may have paid $2.4 million for ivermectin prescriptions for COVID-19 in the week of August 13, 2021 alone. If prescribing and insurance reimbursement were at that level for an entire year, insurers would spend nearly $130 million over a year on the drug, despite a lack of evidence it works.

"Insurers usually don't cover ineffective treatments, or at least make patients pay for most of the cost," said Kao-Ping Chua, MD, PhD, the health care researcher from U-M who led the study. "Our study suggests that they are treating ivermectin prescriptions for COVID-19 differently. In doing so, they are reducing barriers to an ineffective drug that some are using as a substitute for COVID-19 vaccination or evidence-based treatments."

Unless strong new evidence comes to light, the researchers argue that insurers should require doctors to justify prescribing ivermectin during the pandemic by filling out a prior authorization form.

While they acknowledge this could make it harder for patients to get ivermectin for its FDA-approved indications, they believe the number of these patients would be low. As evidence, they pointed to a CDC study showing that only about 3,600 ivermectin prescriptions were filled each week in the U.S. before the pandemic.

"To be clear, clinicians may still prescribe ivermectin for COVID-19 and patients can choose to pay for these prescriptions themselves. Our point is simply that insurers shouldn't cover these prescriptions unless ivermectin proves to be an effective COVID-19 treatment," said Chua, a pediatrician at Michigan Medicine's C.S. Mott Children's Hospital and the Susan B. Meister Child Health Evaluation and Research Center.

The U.S. Food and Drug Administration and the World Health Organization have both said oral ivermectin should not be used for COVID-19 purposes, except in clinical studies.

More about the findings

Using private insurance and Medicare Advantage claims from December 2020 through the end of March 2021, the authors identified and examined 5,600 prescriptions for oral ivermectin that weren't written for a parasitic infection, the main reason that ivermectin is prescribed other than COVID-19.

The total cost per prescription was $58 for private plans, which paid 61% of this amount, or about $36. The total cost per prescription was $52 for Medicare Advantage plans, which paid 74% of this amount, or about $39. The rest of the cost was paid by patients.

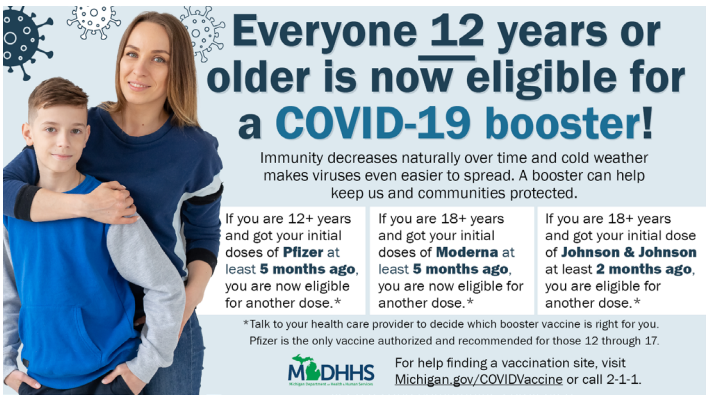
The authors then estimated that all but 3,600 of the 88,000 ivermectin prescriptions filled in the week of August 13, 2021 were for COVID-19. Assuming that the study's results generalized to these prescriptions, the authors estimated that private and Medicare plans paid $2.4 million for the prescriptions in this week alone.

The study team, which included U-M health care researcher Nora Becker, MD, PhD. and Boston University Questrom School of Business researcher Rena Conti, PhD., previously published research showing how much patients may have to pay now that insurers have stopped waiving bills for COVID-19 hospitalizations.

"It's odd that insurers are covering an ineffective treatment like ivermectin even though they are trying to decrease their costs by billing patients again for COVID-19 hospitalizations," says Chua, who along with Becker is a member of the U-M Institute for Healthcare Policy and Innovation.

Paper cited: "US Insurer Spending on Ivermectin Prescriptions for COVID-19" *JAMA*, **DOI: 10.1001/jama/2021.24352**

This article was originally posted on the Michigan Medicine News website. ✦



Henry Ford Macomb Hospital

HENRY FORD HEALTH SYSTEM UNVEILS COVID-19 TRIBUTES

In late October, Henry Ford Health System began unveiling custom art pieces reflecting and celebrating the diversity of its team members and their unique experiences through the COVID-19 pandemic.

This project, made possible through Henry Ford's COVID-19 Relief Fund, is part of the health system's ongoing efforts and initiatives to provide direct emotional support for team members.

"As an organization we understand that art is synonymous with healing," said Henry Ford Health System President & CEO Wright Lassiter III. "A healing arts journey like this frankly represents fuel. Fuel that should uplift our souls and feed us when we're feeling down. Art transforms, art inspires, and art uplifts."

Throughout the creation process, artists have engaged with Henry Ford team members to understand what they have endured both personally and professionally through the pandemic. Their collective experiences are infused into the resulting work.

Artist Sue Majewski in her home studio

"The artwork will be prominently displayed as an ongoing tribute to our teams and their dedication, resiliency, compassion and perseverance in overcoming this truly difficult time in our history," said Megan Winkel, Lindsay Anderson Healing Arts Curator and manager of the Healing Arts Program at Henry Ford Cancer Institute.

The artists were chosen by committees of team members at each of the 10 Henry Ford Health System locations where the art will be installed. The selected artist for Henry Ford Macomb Hospital is Sue Majewski.

HENRY FORD MACOMB HOSPITAL NATIONALLY RECOGNIZED WITH AN 'A' LEAPFROG HOSPITAL SAFETY GRADE

Henry Ford Macomb Hospital received an "A" Leapfrog Hospital Safety Grade for fall 2021. This national distinction recognizes Henry Ford Macomb Hospital's achievements in protecting patients from harm and error in the hospital.

The Leapfrog Group, an independent national watchdog organization, assigns an "A," "B," "C," "D," or "F" grade to general hospitals across the country based on over thirty national performance measures reflecting errors, injuries, accidents and infections, as well as systems hospitals have in place to prevent harm.

The Leapfrog Hospital Safety Grade is the only hospital ratings program based exclusively on hospital prevention of medical errors and harms to patients. The grading system is peer-reviewed, fully transparent and free to the public. Grades are updated twice annually, in the fall and spring. This is the seventh consecutive "A" rating for Henry Ford Macomb Hospital.

BEAM SIGNING CEREMONY MARKS MILESTONE ON MAJOR EXPANSION AT HENRY FORD MACOMB HOSPITAL

Hundreds of staff members, physicians and community leaders made their mark on the future of healthcare when they signed one of the final steel beams that will be used in the construction of Henry Ford Macomb Hospital's new north tower. The beam will be raised into place on January 5, 2022 as part of the new tower entrance.

"We are proud to celebrate another milestone in this historic expansion project," said Barbara Rossmann, president and CEO of Henry Ford Macomb Hospital. "Our progress since our June groundbreaking event is remarkable. The fact that we remain on target for a spring 2023 opening is a testament to our partners and team members."

Henry Ford Macomb, part of the Henry Ford Health System, is undergoing the largest expansion and renovation in its history with a new five-story, 225,000-square-foot addition featuring 160 private patient rooms that can be converted to manage critically ill patients on par with an Intensive Care Unit. Inpatient units in the existing hospital will also be renovated to create spacious private rooms.

Once completed, the project will transform the hospital campus for years to come as the county's first hospital to provide all 361 of its licensed beds as private rooms for the safety and convenience of patients.

The $318 million expansion and renovation represent the largest healthcare investment in the county's history by a health system.

"The pandemic has challenged all of us in many ways," said Rossmann. "While we work to care for record numbers of patients, both COVID related and those needing tertiary level care – we live with hope in the building being constructed, and in the support of our community."

continued on page 14

Construction on the expansion is expected to be completed in 2023, with renovation of existing patient rooms complete in 2024. Barton Malow/Dixon is the construction firm and AECOM is managing the architectural and engineering design.

The hospital will remain fully operational throughout the expansion and renovation. For full details on the project, visit **www.HenryFord.com/MacombTransformation**.

Top: Barbara and Jim Rossmann, Middle: MJ Vogt and Tina Lavinio Mattinen, Bottom: Dr. Samer Kazziha

HENRY FORD HEALTH SYSTEM PARTNERS WITH DTE ENERGY TO REDUCE GREENHOUSE GAS EMISSIONS, IMPROVE IMPACT ON ENVIRONMENT

Henry Ford Health System announced a new partnership with DTE Energy that will dramatically reduce its greenhouse gas emissions in the next decade, help combat pollution and climate change, and help reverse environmental inequities in Detroit.

Through DTE's voluntary renewable energy program, MIGreenPower, Henry Ford will begin purchasing wind and solar energy. The goal is that beginning in 2023, 10% (approximately 19,100 megawatt hours) of Henry Ford's total electricity purchased from DTE will come from Michigan-made renewable energy, increasing incrementally to 100% by 2029.

"Sustainability is an integral part of building strong, healthy communities," said Bob Riney, Henry Ford Health System's President of Healthcare Operations and Chief Operations Officer. "At Henry Ford, health equity is at the foundation of everything we do. It's an unfortunate fact that low-income communities and communities of color are disproportionately impacted by poor environmental conditions, which are exacerbated by climate change. By investing in clean, renewable energy and sustainable infrastructure, we aim to address health disparities and the growing impacts of climate change region-wide, especially in our historically marginalized communities."

Henry Ford's clean energy commitment with DTE will begin as soon as the energy company's infrastructure comes online, likely in late 2023. The initial purchase will reduce the organization's greenhouse gas emissions by roughly 13,536 metric tons, the equivalent of removing 2,944 passenger vehicles from the road each year.*

The system has been working with DTE and other partners to implement other energy conservation measures, like lighting replacement and HVAC upgrades, that are yielding significant reductions in greenhouse gas emission. Henry Ford is also working with other utility providers to identify further energy savings opportunities, including renewable energy options.

"We are doing this because we are deeply committed to the health of our communities and dedicated to sustainable solutions that improve health and wellness," said Chip Amoe, Henry Ford's Director of System Sustainability. "All of our sustainability initiatives are designed to have a direct impact on improving the health of the employees, patients and communities we serve."

**Avoided emissions and equivalencies are based on eGrid 2019 marginal non-baseload emissions factors by subregion and the Environmental Protection Agency equivalencies calculator at http://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator*

McLaren

McLaren Macomb Hospital

RENAMED MCLAREN MACOMB SURGERY CENTER RECOGNIZES FAMILY OF LOCAL BUSINESS LEADER

McLaren Macomb has announced that the surgery center located on the hospital's main Mount Clemens campus will be officially known as the Joseph P. Aesy Surgery Center. The dedication and sign unveiling on October 27 follows a generous donation to the hospital by local business leader Jim George in honor and remembrance of his late father-in-law and the grandfather to his children.

George has been associated with the hospital for more than 20 years, beginning as a significant financial donor before joining the hospital's board of directors in 2000. He was named chairman in 2015.

He joined the board at the system level of McLaren Health Care in 2011, and he was appointed board secretary in 2019.

"I'm very proud to support McLaren Macomb in a significant way given its importance to the community," George said. "We are very fortunate to have this world-class facility providing health care to local residents close to home."

The $3 million donation to support the construction and naming of the surgery center is the latest in his continuing dedication to McLaren Macomb and its mission to provide world-class health care to the Macomb County community.

"Jim George's dedication, leadership and support of our organization has thoroughly solidified his spot as a significant piece of our hospital's history," said Tom Brisse, president and CEO of

McLaren Macomb. "His and his family's continuing support of the community's health care, and also choosing to dedicate the surgery center in honor of his father-in-law speaks highly to the family's collective character."

Opened in 2005 following two years of construction, the two-story surgery center at McLaren Macomb represented a 151,000-square-foot expansion of the hospital, the most significant project in the hospital's history at that time, adding leading edge surgical technology across ten operating rooms (among several more exam rooms) capable of accommodating a range of procedures performed by the hospital's staff of surgeons.

KARMANOS CANCER INSTITUTE RECEIVES MULTI-MILLION DOLLAR GRANT TO DETERMINE WHY ADVANCED CANCER TREATMENT FAILS AFRICAN AMERICANS

Research will examine racial disparities in effectiveness of immunotherapy

The Barbara Ann Karmanos Cancer Institute and Wayne State University recently received a $2,997,215 federal grant to help determine why African Americans show poorer responses than whites when treated with one of the most advanced immunotherapies for lung cancer. The specific focus of the grant is to study immune checkpoint inhibitor (ICI) treatment for metastatic non-small cell lung cancer.

The grant is through the NCI's SPORE, or Specialized Program of Research Excellence, which funds collaborative, interdisciplinary translational cancer research. It will fund two projects under the title Reducing Cancer Health Disparities in Detroit.

Project 1: Characterizing race-specific immune profiles with respect to the tumor environment and host genetic background to determine their contribution to response to ICIs

Project 2: Understanding racial differences in patients' responses to ICI treatment

The projects will be led by principal investigators Ann Schwartz, PhD, MPH, Deputy Center Director, Karmanos Cancer Institute and Professor and Associate Chair of Oncology, Wayne State University School of Medicine and Gerold Bepler, MD, PhD, Thoracic Oncologist, President and CEO of Karmanos Cancer Institute.

Recent breakthroughs in immunotherapy, particularly ICIs with Food and Drug Administration approval, have offered significant advancements for lung cancer treatment. Unfortunately, African American patients have accounted for less than four percent of ICI clinical trial representation. In the limited data available, African Americans show poorer responses to ICIs than whites, contributing to racial disparities in cancer treatment.

Overall, African Americans continue to have worse outcomes after a lung cancer diagnosis than whites, and there are known differences between African Americans and whites in many aspects of cancer treatment, including time to initiation and dose of chemotherapy, symptom burden and treatment of side effects.

Poorer response to treatment and worse outcomes are compounded because lung and bronchus cancers were leading sites of cancer diagnosis among African American men and women from 2019 to 2021, according to the American Cancer Society. Lung and bronchus cancers were the number two cause of cancer death in African American people, following prostate cancer in men and breast cancer in women.

Work funded by the grant will provide the basis to move toward a more race-inclusive, equity-focused, precision medicine approach to the use of ICIs and serve as a model for future research on other cancer sites and new agents.

"With this grant, we will work to address racial disparities in Metropolitan Detroit, a uniquely important underserved population where great cancer disparities exist," said Ann Schwartz, PhD, MPH, one of two principal investigators for the study. "Racial disparities in cancer outcomes will likely widen without a comprehensive understanding of the biologic mechanisms driving treatment response in diverse populations and the applicability of clinical guidelines to all populations."

In their efforts to understand racial treatment-response differences, researchers will directly evaluate sociodemographic, individual and disease-specific predictors of response to ICI treatment in African American and white patients. While ICIs hold promise for improved outcomes, little is known about whether potential predictors of patient-reported side effects and quality of life and immune-related adverse events vary by race.

By identifying drivers of potential disparities, health care professionals can better identify patients at high risk for side effects and immune-related adverse events, which are a significant concern. Health care providers can also develop interventions to reduce risk factors, thereby improving patients' quality of life and reducing racial disparities in outcomes.

Unfortunately, little is known about potential racial differences in response to ICI treatment. This is largely due to a lack of inclusion of African American patients in the clinical trials leading to FDA approvals. Thus, there is a critical need to explore whether African American and white patients are affected differently by side effects related to ICI treatment. ✦

Open Notes in Healthcare: The Good, the Bad, and the Ugly of the Cures Act

By: Chad Anguilm, MBA, Richard F. Cahill, JD, and Kathleen Stillwell, MPA/HSA, RN

On April 5, 2021, a requirement of the 21st Century Cures Act went into effect: Patients must be able to access information in their EHRs "without delay." (This requirement does not apply to paper records.) The Cures Act prohibition against information blocking, often referred to as an "open notes" provision, provides patients with transparency in the outcomes of their healthcare via convenient access to information in their EHR, which can positively or negatively impact the patient-doctor relationship.

The good news: Many patients feel better about their provider after reading a note. Positive effects on the patient-provider relationship may be most significant among vulnerable patients, such as those with fewer years of formal education.

The bad news: Concerns about open notes mainly revolve around the potential for conflicts with patients and potential time conflicts.

Concerns include:

- Timing: The originally planned implementation date for the open notes provisions in the Cures Act was November 2020. Because of the COVID-19 pandemic, this was pushed back to April 2021.
- Uncertainty about the documentation process: Most patients will not understand clinical shorthand, and providers may need added time for explanation.
- Technology: Some EHR vendors are still racing to provide services that allow practices to remain in compliance with the Cures Act.

The ugly news: More frequent requests for records changes from patients could increase already weighty administrative burdens on providers. Worse, some of these requests will be for changes providers cannot support, and making time for careful conversations with patients and providing written responses for requests that are rejected will be a challenge.

When composing notes, certain simple strategies will raise the odds that notes will be well understood and well received. Beyond being clear and succinct, strategies for success include composing at least a portion of the note as instructions directly addressed to the patient and providing a list of commonly used medical terms and abbreviations.

For an in-depth review of strategies for success when composing notes, see **12 Strategies for Success With Open Notes in Healthcare: The Cures Act**

Unless an exception applies, clinical notes must not be blocked, but the Cures Act allows for a fairly long list of specific, well-delineated exceptions.

For information regarding exceptions to open notes, please see **What Open Notes Exceptions Does the Cures Act Allow?**

Chad Anguilm, MBA, is Vice President, In-Practice Technology Services, Medical Advantage, part of TDC Group. Richard F. Cahill, JD, is Vice President and Associate General Counsel, The Doctors Company, part of TDC Group. Kathleen Stillwell, MPA/HSA, RN, is Senior Patient Safety Risk Manager, The Doctors Company, part of TDC Group. ✦

MSMS
MICHIGAN STATE MEDICAL SOCIETY

By: Daniel M. Ryan, MD, MSMS Region 2 Director

DON'T BE SURPRISED BY THE FEDERAL 'NO SURPRISES ACT'

In 2020, the Michigan Legislature and United States Congress each enacted laws to regulate unexpected or "surprise" medical bills that a patient receives after receiving health care services from an out-of-network or nonparticipating provider. Last year, Michigan and federal agencies issued administrative rules and guidance to further implement the legislation, including with respect to fee limitations, transparency, and options for dispute resolution between providers and payors. Navigating these requirements just became more manageable with the Michigan State Medical Society's (MSMS) **Surprise Medical Billing Guide** prepared by MSMS Legal Counsel.

This Guide addresses frequently asked questions, compares Michigan and federal laws and regulations, and offers template documents to help you meet disclosure and transparency requirements. For more information, contact Stacey P. Hettiger **shettiger@msms.org**.

Below are key provisions on the No Surprises Act that began January 1, 2022, which physicians and other providers need to be aware.

Patient Balance Billing Protections – Under the federal law, these protections apply to emergency services, air ambulance transportation, post-emergency stabilization services, and non-emergency services provided by out-of-network providers at in-network facilities. Physicians, hospitals, and other covered providers who furnish care protected by the No Surprises Act are no longer permitted to bill patients for more than the in-network cost sharing amount. Instead of billing patients directly, out-of-network providers will submit the bill directly to the patient's health plan. Health plans are required to notify providers of the applicable in-network cost sharing amount, make an initial payment, and send the patient an explanation of benefits indicating what the plan has paid and what the patient still owes the out-of-network provider.

The No Surprise Act permits out-of-network providers at in-network facilities to balance bill patients for certain services if notice and consent requirements are met within specified time periods.

Good Faith Estimate – Regardless of setting, all physicians, facilities, and other health care providers must provide uninsured and self-pay patients with a good faith estimate (GFE) of the expected charges, expected service, and diagnostic codes of scheduled services. In order to comply with this requirement, patients scheduling a service will need to be asked if they are covered by a health plan and, if so, whether they intend to have their claim(s) for the service submitted to the plan. The GFE must be provided upon request or upon scheduling care at least one or three business days in advance (depending on when the service is scheduled) and be written in clear and understandable language.

Disclosures – Physicians, facilities, and other health care providers are required to disclose patient protections against balance billing. This disclosure must include how to report violations and be posted in a prominent location at the practice or facility, posted on a public website (if applicable), and provided to the patient.

Provider Directories – In order to ensure up-to-date information is available for patients, physicians, facilities, and other health care providers are required to provide health plans with directory information at specified time periods.

Resources

- **Surprise Medical Billing Guide**
- **AMA No Surprises Act Toolkit**
- **MSMS Grand Rounds Webinar Series: Navigating the No Surprises Act**

MSMS AND MICHIGAN PHYSICIANS SUPPORT NEW TELEHEALTH PARITY LEGISLATION

The following is a public statement from Pino D. Colone, MD, president of MSMS, in response to the introduction of House Bill 5651, legislation requiring insurers to cover and reimburse telehealth services the same as if the services were provided in-person.

"The introduction of House Bill 5651 is an important first step towards ensuring Michigan's patients continue to enjoy access to the telehealth services that have proven to be so crucial during this pandemic."

"One advancement we've seen during the COVID-19 pandemic has been the emergence and widespread embracing of telemedicine. Over the past several months, telehealth has proven to be a safe, effective, and efficient care delivery method, especially for those living in underserved communities."

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"It's time Michigan joins the 22 other states across the country that have enacted payment and coverage parity legislation, ensuring telehealth service remain a viable option for patients and providers alike throughout the state."

THE DATA IS IN: NEW REPORT DETAILS DEVASTATING IMPACT OF MICHIGAN'S CATASTROPHIC CARE CRISIS ON SURVIVORS, THEIR FAMILIES, AND PROVIDERS

Judd: Legislature must pass "common sense" amendment to protect accident victims

Following the release of a new study tracking the destabilizing long-term impacts of Michigan's 2019 auto insurance law, Michigan Brain Injury Provider Council (MBIPC) president Tom Judd called for a "common sense" amendment to the 45% cut in catastrophic care that has led to Michigan's ongoing catastrophic care crisis.

The independent study, which was conducted by nonprofit public health institute MPHI, found that:

- 1,548 auto crash survivors have been discharged
- 3,049 jobs have been eliminated
- 96 companies are now unable to accept referrals with auto insurance funding
- 21 companies have completely closed down operations
- 140 companies have significantly reduced their services and/or products

"Prior to the implementation of the draconian and irresponsible reimbursement scheme set forth in the 2019 no-fault auto insurance reforms, which arbitrarily slashed rates of essential rehabilitation services and care for auto crash survivors by nearly half, Senate Majority Leader Mike Shirkey dug in his heels and insisted lawmakers needed to see 'data' before making any changes," Judd said. "Despite warnings that waiting for the data they were looking for meant the prolonged suffering of severely injured accident survivors and the loss of care-provider jobs throughout the state, the Republican-led legislature declined to take up a number of bills that could have prevented the catastrophic care crisis, which is now well underway, without changing any other aspect of insurance reform – including consumer cost savings."

Judd said that while some companies reported that they were not impacted in the first four months of the fee cap system, nearly 90% of the 273 respondents said they would be unable to serve auto crash survivors within the next 12 months (including the 184 companies that have already been impacted).

The MPHI report's findings echoed the conclusions of another nonpartisan and unbiased institution. The University of Michigan Poverty Solutions Center's December 2021 **Building on Michigan's Auto Insurance Reform Law analysis** found that "the method used to cap medical fees may be unnecessarily stringent and out of line with national peers, causing a crisis in access to care for victims of catastrophic accidents."

"The Republican-led legislature has not listened to its constituents or the qualified, ethical providers whose mission is to serve Michigan's auto crash survivors," Judd said. "Lawmakers have consistently disregarded pleas for common-sense amendments to the fee schedule so that the crisis in care can end and people can get back to receiving the rehabilitation services and care they need and deserve. Hopefully, Majority Leader Shirkey and his colleagues don't ignore the data they have been looking for from reputable third-party sources like MPHI and University of Michigan."

The MPHI report indicated that two future surveys are scheduled to track ongoing impacts of the reimbursement cap system. Judd said he hoped these surveys are not necessary.

"Further data should not be needed to support the hundreds of news stories across the state that have told the personal stories behind this unfolding tragedy," Judd noted. "The time for action is well past us. Michigan's crash survivors, their families, and their care providers deserve immediate action. House Speaker Jason Wentworth, Senate Majority Leader Mike Shirkey, and the Republican-led legislature must act to end Michigan's catastrophic care crisis now."

MSMS: THE FUTURE OF MEDICINE 2021

The practice of medicine has changed substantially in recent years, due to rapidly developing technologies, emerging research, and a renewed focus on racial equity and the social determinants of health (SDOH). Combine this with the tragic realities encountered with the emergence, spread and confrontation with the COVID-19 pandemic. As Michigan physicians and caregivers work to address these transformations, there's never been a better time for us to look ahead and determine what the future of medicine in Michigan should be.

The Michigan State Medical Society (MSMS) invited Public Sector Consultants to conduct interviews with health care leaders, with a focus on physician voices, to gather input on the most pressing issues in health care, how to address those issues, and the policies needed to support those changes. We also invited input on ways MSMS can support Michigan physicians and improve health care.

MSMS received a tremendous amount of high-quality, actionable feedback. Some of the cross-cutting themes embedded in this research include:

- Strong support for increased use of team-based and integrated care models and value-based and risk-based pay ment models
- Recognition of the importance of SDOH and health equity to good medicine and a healthy population

- Physician leadership as a requisite for meaningful change
- The need for payer alignment and transparency to reduce administrative burden
- The need for multidisciplinary and cross-sector partnerships to implement meaningful change

We also identified other key concerns for the future of health care, including the need for greater access, affordability, and quality.

Now that this visioning work and research has been completed, we are eager to share the results with you. To download the final report summarizing the process and findings, please visit **http://MSMS.org/FOM2021**.

As leaders and advocates, we must use these findings to work together to achieve the results we want for your patients and your practices. The results we have compiled for you are designed to provide all of us with constructive, well-researched guidance so we can begin creating a shared future that is bright with promise. ✦

THIS IS THE YEAR TO REFORM MEDICARE PAY, BOOST TELEHEALTH

By: Jennifer Lubell, Contributing AMA News Writer

The AMA's advocacy team had a busy year in 2021. They worked on several fronts, tackling the COVID-19 pandemic through vaccination campaigns, averting a nearly 10% cut in Medicare physician payments, and collaborating on a lawsuit to stop implementation of a narrow but critical provision of the No Surprises Act.

"There really was no let up from day one," Todd Askew, the AMA's senior vice president of advocacy, said during a recent episode of the "AMA Moving Medicine" series. "It was just a tremendous, tremendous year of important items and accomplishments from January straight through December."

Looking ahead to 2022, rebuilding physician payment models of care presents the biggest opportunity for AMA advocacy, noted Askew. "It's not going to be a slam dunk and it's not going to be done in one year, but if we're going to start on this journey, we've got to sit down and get going and this is the time to do it," he said.

Fundamental rethink on payment

Medicare cuts to physicians play on repeat each year, said Askew: "There's no stability, there's no predictability."

The "way the payment structure is designed under" the federal government's Merit-based Incentive Payment System, with four separate, poorly aligned programs "doesn't make any sense," he addeed. Opportunities to pursue alternative payment models never fully came to fruition. Additionally, the system doesn't keep up with inflation.

Budget neutrality provides increases for certain services or type of provider, but no new money, he emphasized. Other Medicare providers have built-in updates, a medical economic index or inflationary growth factor, that reflect an increase in the cost of providing services. Physicians have no such benefit, said Askew.

"A legacy of multiple experiments of different systems and action taken to avert a massive cut a decade ago" has led to this result, he explained. Physicians need to pull together and come to some agreement on how to provide sustainable payment rates that reflect increasing costs of care and promote innovative payment models, he said.

The AMA's advocacy team has been speaking with leaders across the Federation of Medicine about reforming the way Medicare pays physicians. "I think there's enthusiasm and a

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strong agreement that we need to sit down together and come up with a new way of doing this. I think that's the greatest opportunity that we have in 2022," said Askew.

Recognizing telehealth's value

This year also presents a tremendous opportunity to promote and improve access to telehealth, which has been "one of the few bright spots" of the pandemic, said Askew.

Physicians and payers once reluctant to embrace the technology are now using it to triage patients or provide ongoing care outside of physician offices and hospitals. "A lot of unnecessary exposure was avoided. The value of telehealth has really been proven," he said.

Statutory changes are needed to preserve this option for Medicare patients beyond the COVID-19 public health emergency, he added.

AMA advocacy made a difference in several critical areas in 2021. Passage of the American Rescue Plan Act of 2021 "opened up access to Affordable Care Act coverage to many millions of more people, both through increased access to subsidies and other improvements to the program," said Askew. The Supreme Court's dismissal of a significant challenge to the ACA was another big win.

The AMA also worked to support physicians and the health care system to promote COVID-19 vaccinations, said Askew. The AMA will continue to work with doctors, hospitals, employers, unions and the government to get as many people vaccinated as possible "because vaccination is the way out of this," he said of the pandemic.

2022 A CRITICAL YEAR TO ADDRESS WORSENING DRUG-OVERDOSE CRISIS

By: Bobby Mukkamala, MD, Michigan otolaryngologist, chair of the AMA Board of Trustees and chair of the AMA Substance Use and Pain Care Task Force

As the COVID-19 pandemic continues to devastate families and communities across the U.S., we cannot ignore that illicit fentanyl is fueling the nation's drug overdose epidemic and primarily responsible for the deaths of more than 100,000 people last year alone.

Unless policymakers take action in 2022 to update rules and laws that are enabling our worsening overdose epidemic, more Americans will die, and more families will suffer preventable tragedies.

The stakes are high. Drug-overdose deaths are an epidemic in the U.S., touching virtually every state. About 60% of those deaths in the past year are linked to illicitly manufactured or adulterated fentanyl. With the U.S. Drug Enforcement Administration seizing nearly 10 million fake pills last year—many laced with counterfeit fentanyl—we must act with evidence-based public health interventions to limit the risks and harms of overdose.

Knock down barriers

First, it's far past time for policymakers and other key stakeholders to remove barriers to evidence-based treatment for substance-use disorders. Multiple states cut addiction treatment programs from their yearly budget in 2020. Ongoing state budgetary challenges do not help.

All 50 states and the District of Columbia reported a spike or increase in overdose numbers during the COVID-19 pandemic. Action is required to address this unprecedented situation, including prohibiting health insurance companies from using administrative tactics such as prior authorization to delay and deny care to those with a substance use disorder.

More than 90% of doctors reported delays in treatment while waiting for health insurers to authorize necessary care, according to the AMA's latest research in 2020. And nearly 80% of physicians said authorization delays have forced some patient to abandon treatment altogether.

Furthermore, courts, jails and prisons must ensure access to medications to treat opioid-use disorder. And we urge all state insurance departments and attorneys general to show the leadership necessary to enforce mental health and substance-use disorder parity. Removing barriers to evidence-based care also will help address long-standing racial and gender inequities, including the fact that overdose deaths are rising most rapidly among Black people. Improving access to evidence-based treatment is an effective strategy for improving equity.

Second, harm reduction must be more than just increasing access to naloxone, the opioid-related overdose-reversing drug. More physicians than ever are prescribing naloxone, but that's just a first step. The AMA urges changes to state laws that allow for emergency departments, for example, to distribute naloxone to anyone who has experienced an overdose.

We further urge all states to broaden their Good Samaritan statutes to provide comprehensive civil and criminal immunities for anyone who calls for help during an overdose or experiences an overdose. And we repeat our call for all naloxone manufacturers to submit applications to the Food and Drug Administration to make their products available and affordable over the counter.

This includes having FDA remove the "prescription" status for generic forms of injectable naloxone that harm-reduction organizations rely upon to help save tens of thousands of people each year. There is no justifiable reason for keeping naloxone behind the counter other than pharmaceutical industry profit.

Make drug-checking supplies legal

Third, while naloxone has saved the lives of tens of thousands, a cost-effective, safe and commonsense solution to help people who use substances non-medically is to decriminalize fentanyl test strips and other drug-checking supplies.

Unfortunately, 32 states view these potentially life-saving tests as illegal drug paraphernalia, according to the Legislative Analysis and Public Policy Association. The AMA has model state legislation to decriminalize fentanyl strips and other drug-checking supplies. A single fentanyl test strip costs $1, is easy to use, and only takes a couple of minutes to show the results. These test strips provide crucial answers to a person from one testing sample that could potentially save a life.

Finally, we urge states to also decriminalize and make sterile needle and exchange services more widely available. After all, substance-use disorders are medical conditions that require treatment, not punishment and judgement. The American Rescue Act included $30 million "to support community-based overdose prevention programs, syringe services programs, and other harm reduction services."

We agree with public health experts that the Centers for Disease Control and Prevention and the Substance Abuse Mental Health Services Administration "should act expeditiously to award these grants directly to community-based harm reduction organizations who will use them to provide syringes and other supplies to the hundreds of thousands of already vulnerable individuals made even more vulnerable by the twin epidemics of overdose and COVID-19."

These steps will not solve all of the challenges in the nation's drug overdose epidemic, but they are evidence-based strategies that will save lives. We must further address social determinants of health such as housing, employment and transportation that help people with substance use disorders access care. There is much to do. The AMA urges all stakeholders to join us to make it happen.

HOW PHYSICIANS, HEALTH SYSTEMS CAN CUT STIGMA ON SEEKING HELP

By: Sara Berg, MS, Senior AMA News Writer

With a new year comes more opportunities for change, especially to reduce physician burnout and improve well-being. Many people have already started to reprioritize what they want to be doing with their lives.

But for Mark Greenawald, MD, a family physician at Carilion Clinic in Roanoke, Virginia, the hope is that physicians will start to push back against some of the things they have been tolerating for a long time. This means creating better environments and cultures to decrease the stigma around seeking help so that physicians can thrive.

"What we're starting to see more of is that help-seeking behavior where people are starting to say, 'I do need help.' And we're starting to create a culture where it's safer to do that," said Dr. Greenawald.

Share your burnout stories

When Dr. Greenawald has the opportunity, he shares his burnout and distress stories with other physicians.

"My first foray into seeking help—to the level of professional help—came after I had a very tragic obstetrical patient who died in labor, and the baby was neurologically devastated," he said. "And it took me an entire year of silent suffering before my wife finally said, 'Enough. You can't continue in the way that you are right now. This is no longer OK.'" Dr. Greenawald visited a therapist and "she gave me my life back again," he said. "I was able to realize that I lost a year of my life when I was a father of three young children, when I was a husband, when I was trying to take care of a busy medical practice. I lost that year because emotionally I was not present for most of it." "I don't want that to happen to anybody else ... because we know it's happening right now and it's tragic," he said, noting that it's key "to tell our stories—particularly for those who are in leadership positions, who are looked upon as opinion leaders—and be able to say it's okay to reach out and seek help."

Turn to peer support

One thing that hasn't changed during the COVID-19 pandemic is the need for peer support. The need has only become more urgent.

Peer support is often about "reaching out when something bad has happened, and so it's a reactive way of peer support," said Dr. Greenawald. "In that model, there's somebody who is the helper and somebody who is the helped, if you will."

"What I have started thinking more and more about is what does peer support look like beyond that?" he said. "Rather than just thinking about it as—I'm going to reach out when you need help—I'm going to be reaching out all the time. And I'm going to be looking for opportunities not just to help you, but to build you up."

That way, "hopefully, I'm increasing your resistance to some of the bad things that can come along—some of the stressors that can come along the way," said Dr. Greenawald.

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Connect with colleagues

Peer support commonly consists of helping a colleague who is in crisis. But it also consists of peer-to-peer support, which means "buddying up in different groups, different specialties," said Dr. Greenawald. It is about saying, "no one should care alone."

That means "making sure that you're traveling that journey with a buddy" as well as a mentor, he said. "So having folks who we are looking to not just mentor us in terms of our professional career, but in terms of our professional life."

WHY TALK OF AI'S TRANSFORMING HEALTH CARE IS PREMATURE

By: Andis Robeznieks, Senior AMA News Writer

Some applications of augmented intelligence (AI), often called artificial intelligence, may indeed be saving lives, reducing physician burnout, making health care more efficient and have the potential to do much more. But those who are proclaiming that AI is changing health care as we know it need to slow down.

"There are some incredible uses right now, but I think the whole concept of it transforming health care in its present state—we probably ought to pump the brakes just a little bit on that," said Brett A. Oliver, MD, chief medical information officer at Baptist Health Medical Group, an AMA Health System Program member based in Louisville, Kentucky.

Dr. Oliver, a family physician, spoke during a AMA Insight Network virtual interview that covered his organization's AI journey.

Where AI proves its value

Baptist Health has a successful AI tele-stroke program that identifies potential stroke patients whose conditions are "amenable to procedures."

"With stroke, like a heart attack, time is tissue, and so, the faster we can get that information to the clinicians that can intervene, the better," Dr. Oliver said.

Another AI use being tested involves converting a securely recorded office visit into a structured physician note. This has the potential to improve patient satisfaction, reduce physician burnout and improve documentation.

"We're really excited about that," he said. "Most importantly, it's getting clinicians away from the computer and engaged again with the patient—that's the main goal with that."

Baptist also developed a COVID-19 related tool that identifies patients who may be more safely treated via telehealth than an in-person visit. Conversely, another trial has been testing an application identifying which COVID-19 patients can more quickly be discharged from the hospital and sent home with a continuous monitoring device.

While that trial is lacking a control arm, Dr. Oliver says about 340 patients have been sent home using this application and none have needed to be readmitted.

But before anyone claims these applications are transforming health care, Dr. Oliver said quality questions need be resolved and end users need to be assured that the data used to create AI algorithms is sound and matches the patient populations it is meant to serve.

Dr. Oliver added that he recognizes some algorithms may be generated using proprietary methods, but then, in those cases, there needs to be an official, disinterested third party who is allowed to look into the AI "black box" and assure users that its algorithms are sound and will help—and not harm—patients or introduce bias.

Physicians "want to understand why," Dr. Oliver explained. If they don't understand why the algorithm generated the clinical decision that it did, "buy-in is a struggle."

First steps on the journey

For organizations just starting their AI journey, Dr. Oliver recommended focusing on applications that produce actionable data that can be used toward solving a priority problem such as improving access or reducing physician burnout.

Dr. Oliver warned beginners that "there are a lot of bright and shiny things out there in the AI world that are really cool," but will only waste their time.

For successful AI adoption, an organization needs to first establish data governance policies and then continually train staff.

"It's kind of dry and boring—I get that," Dr. Oliver said. "But if you have strong governance upfront, you have a standardized data intake, evaluation and review processes."

Staff education doesn't have to be formal, he said. But it should be ongoing.

"Don't assume that your colleagues know anything about any of this," Dr. Oliver said. ✦

LEGISLATIVE UPDATE

Take Action and Contact your Legislators

Support Michigan Health Care Workers in HB 5523
Michigan hospitals are asking state senators for support through House Bill (HB) 5523, which will provide critical staffing resources to hospitals and other providers.

The Michigan House of Representatives passed HB 5523 Dec. 14, a COVID-19 supplemental funding bill that allocates $1 billion in federal funds, including $300 million for recruitment and retention bonuses for healthcare settings.

Tell your officials that the needs of our health care providers and their workforce must be prioritized and to immediately appropriate this funding.

Telehealth Parity
Recently introduced House Bill 5651 will require insurers to cover and reimburse telehealth services the same as if the service were provided in-person. This important legislation will go a long way in improving access to care in underserved communities, areas with physician shortages, and areas with limited access to primary care services. It will also ensure telehealth remains a sustainable option for physicians to offer to their patients. **Vote YES on HB 5651**

Nurse Scope of Practice Expansion
Senate Bill 680 will allow for full independent practice for nurse practitioners (NPs). Under the bill, not only would NPs be allowed to provide direct care without physician supervision or collaboration, they would also be allowed to prescribe opioids and other controlled substances. Further, the bill wouldn't even require additional training or education for NPs.
Vote NO on SB 680

Prior Authorization – Health Can't Wait
Senate Bill 247 introduces much-needed transparency, fairness, and clinical validity to the process, ensuring Michigan patients are able to access the care they need when they need it.
Vote YES on SB 247

Support the Push for Behavioral Health Integration
Efforts to reform Michigan's Medicaid program by introducing Senate Bills 597 and 598 are necessary and appreciated. Integrating physical and behavioral health care services is critical to ensure each patient receives the person-centered care required to maximize their overall well-being. However, legislation must include a clinical model that removes existing barriers and care delays by advancing seamless integration amongst clinicians across specialties and care settings.

SBs 597 & 598 take positive steps toward needed integration, however, further improvements are necessary. **Urge Your Senator to recognize the key role primary care plays in the delivery of efficient, effective, and coordinated behavioral health services.**

Ensure Safe Drinking Water in Michigan Schools
Senate Bills 184 and 185 will require schools to install filtered drinking water stations that meet NSF standard 53 for lead reduction. By bypassing the current slow and costly "test and tell" method and simply installing filtered drinking water stations, children are better-protected sooner and in a more cost-effective manner. **Vote YES on SBs 184-185**

2021-2022 Macomb County Legislator Contact Guide

MICHIGAN SENATE

Senate District 8
Sen. Doug Wozniak (R)
5200 Binsfeld Bldg.
(517) 373-7670
SenDWozniak@senate.michigan.gov

Senate District 9
Sen. Paul Wojno (D)
6300 Binsfeld Bldg.
(517) 373-8360
SenPWojno@senate.michigan.gov

Senate District 10
Sen. Michael MacDonald (R)
4200 Binsfeld Bldg.
(517) 373-7315
SenMMacdonald@senate.michigan.gov

Senate District 25
Sen. Dan Lauwers (R)
S-2 Capitol Bldg.
(517) 373-7708
SenDLauwers@senate.michigan.gov

MICHIGAN HOUSE

House District 18
Rep. Kevin Hertel (D)
697 Anderson Bldg.
(517) 373-1180
KevinHertel@house.mi.gov

House District 22
Rep. Richard Steenland (D)
786 Anderson Bldg.
(517) 373-0854
RichardSteenland@house.mi.gov

House District 24
Rep. Steve Marino (R)
788 Anderson Bldg.
(517) 373-0113
SteveMarino@house.mi.gov

House District 25
Rep. Nate Shannon (D)
789 Anderson Bldg.
(517) 373-2275
NateShannon@house.mi.gov

House District 28
Rep. Lori Stone (D)
792 Anderson Bldg.
(517) 373-1772
LoriStone@house.mi.gov

House District 30
Rep. Diana Farrington (R)
794 Anderson Bldg.
(517) 373-7768
DianaFarrington@house.mi.gov

House District 31
Rep. William Sowerby (D)
795 Anderson Bldg.
(517) 373-0159
WilliamSowerby@house.mi.gov

House District 32
Rep. Pamela Hornberger (R)
796 Anderson Bldg.
(517) 373-8931
PamelaHornberger@house.mi.gov

House District 33
Rep. Jeff Yaroch (R)
797 Anderson Bldg.
(517) 373-0820
JeffYaroch@house.mi.gov

House District 36
Vacant
(517) 373-0843

COMMITTEES

MI House – Health Policy
Lori Stone (D), District 28

MI House – Appropriations
Pamela Hornberger (R), District 32
Steve Marino (R), District 24
Jeff Yaroch (R), District 33

MI House – Insurance
Richard Steenland (D), District 22
Lori Stone (D), District 28

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MI Senate – Health Policy
Michael MacDonald (R), District 10
Paul Wojno (D), District 9

MI Senate – Appropriations
Michael MacDonald (R), District 10

Macomb County Medical Society
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