# HEALTH CARE LAW ADVISOR ALERT: ESTABLISHED U.S. PUBLIC HEALTH PRECEDENT ON MANDATORY VACCINATION REQUIREMENTS UPHELD (AT LEAST FOR NOW)

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American law long has recognized the authority of government officials to address public health emergencies. *See, e.g., Gibbons v. Ogden*, 22 U.S. 1, 205 (1824) (recognizing the "power of a State, to provide for the health of its citizens").

More than a century ago, the U.S. Supreme Court decided the seminal case on the power of the states to respond to a public health crisis in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), where it affirmed the constitutionality of a state statute authorizing local health boards to require residents to be vaccinated against smallpox. As explained in *Jacobson*, the authority to respond to a public health crisis must be "lodged somewhere," and it is "not an unusual, nor an unreasonable or arbitrary, requirement" to vest that authority in officials "appointed, presumably, because of their fitness to determine such questions." *Id.* at 27. The Court intermittently emphasized the necessity of the state's smallpox vaccination regulation, as well as the utilitarian aspect of rules protecting the many at the expense of the few, but ultimately seemed to rely on the basic police power of the state to regulate public health as the basis for its decision upholding the vaccination requirement. *Id.* at 26, 28, 29, 31.

Due to the COVID-19 pandemic, courts around the country have had the opportunity to revisit the *Jacobson* decision. Last year, the U.S. Supreme Court discussed *Jacobson* in a decision enjoining an executive order by New York's governor establishing certain occupancy limits to combat the spread of COVID-19. In *Roman Cath. Diocese of Brooklyn v. Cuomo*, 592 U.S. ___, 141 S. Ct. 63 (2020), Justice Neil Gorsuch explained *Jacobson*'s imposition on individual rights was "avoidable and relatively modest" and "easily survived rational basis review, and might even have survived strict scrutiny, given the opt-outs [to the smallpox vaccine requirement] available to certain objectors." *Id.*, 141 S. Ct. 63 at 71 (Gorsuch, J., concurring). And Chief Justice John Roberts quoted from *Jacobson*, stating that "[o]ur Constitution principally entrusts '[t]he safety and the health of the people' to the politically accountable officials of the States 'to guard and protect.'" *Id.* at 76 (Roberts, C.J., dissenting) (quoting *Jacobson*, 197 U.S. at 38).

*Jacobson* also played a pivotal role in two cases addressing COVID-19 vaccination

requirements recently considered by the U.S. Supreme Court.

In the first case, *Klaassen v. Trustees of Indiana Univ.,* No. 1:21-CV-238 DRL, 2021 WL 3073926 (N.D. Ind. July 18, 2021), *Pls.' mot. for inj. pending appeal denied,* 7 F.4th 592 (7th Cir. 2021), eight students filed a federal lawsuit seeking to bar enforcement of Indiana University's requirement that its faculty, staff and students be vaccinated against COVID-19, unless exempt from the requirement for religious or medical reasons. Students who do not get vaccinated are restricted from participation in on-campus activities and their class registrations and university identification cards are cancelled. Exempt students are required to wear masks in public spaces while on campus and be tested for COVID-19 two times a week. The plaintiffs claim the University's rules violate the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. *Klaassen,* slip. op. at *1.

In July 2021, the district court denied the plaintiffs' request for a preliminary injunction. *Id.* at *45. It ruled Indiana University's COVID-19 vaccination requirement "isn't forced vaccination" and that the U.S. Constitution permits the school to pursue vaccination "in the legitimate interest of public health for its students, faculty and staff." *Id.* at *46. A few days later, the plaintiffs filed a notice of appeal with the Seventh Circuit Court of Appeals and moved for an injunction against the university's requirements pending appeal. *Klaassen,* 7 F.4th 592.

In early August 2021, the Seventh Circuit denied the plaintiffs' injunction request, citing *Jacobson*. Judge Frank Easterbrook, writing for the three-judge panel, found the case "is easier than *Jacobson"* for two reasons. *Id.* at 593. First, *Jacobson* upheld a vaccination requirement that lacked any exception for adults, but the university's requirement has certain religious and medical exceptions. Second, unlike *Jacobson,* the university's requirements do not require any adult member of the public to be vaccinated. Instead, they are "a condition of attending Indiana University. People who do not want to be vaccinated may go elsewhere." *Id.* The court recognized that "vaccination requirements, like other public-health measures, have been common in this nation" and that "given *Jacobson . . .* which holds that a state may require all members of the public to be vaccinated against smallpox, there can't be a constitutional problem with vaccination against SARS-CoV-2." *Id.* The court found that:

> Each university may decide what is necessary to keep other students safe in a congregate setting. Health exams and vaccinations against other diseases (measles, mumps, rubella, diphtheria, tetanus, pertussis, varicella, meningitis, influenza, and more) are common requirements of higher education. Vaccination protects not only the vaccinated persons but also those who come in contact with them, and at a university close contact is inevitable.

*Id.*

After the Seventh Circuit's ruling, the plaintiffs filed an emergency application for writ of injunction with the U.S. Supreme Court, again seeking to enjoin enforcement of Indiana University's vaccination requirements. *See Klaassen,* Emergency Appl. 21A15 (Aug. 6, 2021). The plaintiffs argued that the university "is coercing students to give up their rights to bodily integrity, autonomy, and of medical treatment choice in exchange for the discretionary benefit of matriculating at IU." *Id.* at 14. But Justice Amy Coney Barrett, the Circuit Justice for the Seventh Circuit, denied the plaintiffs' application without referring it to the full Court for consideration. *Id., denied* (Aug. 12, 2021) (Barrett, J.). At the time of the writing of this article, the plaintiffs' case continues at the district court.

In the second case, *Maniscalco v. New York City Dep't of Educ.*, No. 21-CV-5055 BMC, 2021 WL 4344267 (E.D.N.Y. Sept. 23, 2021), *Pls.' mot. for inj. pending appeal denied*, 2021 WL 4437700 (2d Cir. Sept. 27, 2021), four New York City public school employees filed a federal class action lawsuit seeking to bar enforcement of New York City's requirement that its public school teachers provide proof of COVID-19 vaccination or face suspension without pay. This requirement does not contain a provision allowing teachers to opt-out of vaccination through COVID-19 testing. The plaintiffs claimed different reasons for not wanting to get the vaccine, including the concern of its long term side effects, and argued that the requirement violates their substantive due process and equal protection rights under the Fourteenth Amendment. *Id.*, slip. op. at *1.

On September 23, 2021, the district court denied the plaintiffs' motion for a preliminary injunction against the requirement, ruling that the plaintiffs could not show a likelihood of success on the merits of their claims. Citing *Jacobson,* the court found that the law allows a state to "'curtail constitutional rights in response to a society-threatening epidemic so long as the [public health] measures have at least some 'real or substantial relation' to the public health crisis and are not 'beyond all question, a plan and palpable invasion of rights secured by fundamental law.'" *Id.* at *3 (citation omitted). The court noted that requiring teachers to "take a dose of ivermectin as a condition of employment" might qualify as an improper invasion of rights, but that "mandating a vaccine approved by the FDA does not." *Id*. The court stated "'the Due Process Clause secures the liberty to pursue a calling or occupation, and not the right to a specific job.'" *Id.* (citation omitted).

Later that day, the plaintiffs filed a notice of appeal with the Second Circuit Court of Appeals and moved for an expedited injunction against New York City's vaccination requirement pending appeal. The Second Circuit issued a temporary injunction in favor of the plaintiffs for administrative purposes so that their motion could be considered by a three-judge motions panel. But on September 27, 2021, that three-judge panel denied the plaintiffs' motion and dissolved the temporary injunction. *See Order of USCA as to [No.] 17,* No. 21-CV-5055, No. 19 (E.D.N.Y. Sept. 24, 2021).

After the Second Circuit's ruling, the plaintiffs filed an emergency application for writ of

injunction with the U.S. Supreme Court, again seeking to enjoin enforcement of New York City's vaccination requirement. *See Maniscalco,* Emergency Appl. 21A50 (Sept. 30, 2021). Justice Sonja Sotomayor, the Circuit Justice for the Second Circuit, denied the plaintiffs' application without even waiting for New York City to reply to it, and without referring it to the full Court for consideration. *Id*., *denied* (Oct. 1, 2021) (Sotomayor, J.). This case also continues at the district court at the time of the writing of this article.

While the rise of various COVID-19 requirements inevitably will lead to additional litigation in various courts around the country, at least for now it seems clear that the *Jacobson* decision continues to provide guidance to public health officials, attorneys and the courts around the country on vaccination issues, as it has for over a century.

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# HEALTH CARE LAW ADVISOR ALERT: NEW FEDERAL REGULATIONS TAKE AIM AT HEALTH CARE PROVIDER BILLING

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Health care providers should be aware of new regulations the U.S. Department of Health and Human Services (HHS) and other agencies issued in July that relate to medical billing practices.

Part I of the long-awaited regulations to implement the federal No Surprises Act was published on July 13, 2021. The regulations are applicable for plan or policy years beginning on or after January 1, 2022. HHS, along with the Department of the Treasury and Department of Labor, issued rules that implement the statutory provisions in the No Surprises Act. This federal law, enacted in 2020, was discussed in an earlier blog article. The new regulations mirror the statutory provisions and provide guidance on interpreting and applying the No Surprises Act. In particular, the new regulations clarify the methodology for calculating the qualifying payment amount (QPA)—a calculation that will often be used to evaluate the

amount health plans pay providers for treatment that falls under the No Surprises Act, including out-of-network emergency care. The regulations also outline requirements for certain health care providers to post and provide consumers with a notice related to balance billing restrictions, and the criteria for providers to obtain the consent necessary to balance bill for non-emergency out-of-network services.

The new regulations do not yet address the independent dispute resolution (IDR) process applicable when health plans and providers do not agree on the amount to be paid for out-of-network care that falls under the Act. This IDR process is an important aspect of the No Surprises Act, and the continued uncertainty may make it difficult for health care providers to plan for the coming year. Regulations on this topic are expected to be issued soon.

The federal government is accepting public comments through September 7, 2021, and may modify the regulations based on those comments.

The attorneys who contribute to the Health Care Law Advisor are available to assist health care providers with a variety of legal matters. Please contact us if you need assistance navigating the new regulations.

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## HEALTH CARE LAW ADVISOR ALERT: DON'T BE CAUGHT OFF GUARD BY FEDERAL "SURPRISE BILLING" LEGISLATION

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The federal No Surprises Act was signed into law in December 2020 and becomes effective on January 1, 2022. Although similar state laws exist elsewhere, Wisconsin does not currently have a "surprise billing" law. As a result, many Wisconsin health care providers will need to take steps to ensure they are complying with the requirements of this new federal law, which will impact their billing and revenue cycle practices.

The Act's primary goal is to protect patients from surprise medical bills, including unexpected charges for out-of-network services. The Act protects patients in two important ways that providers should understand.

First, for emergency services, the law prohibits out-of-network providers from balance billing for amounts beyond what the patient would have been required to pay if the services had been delivered in-network.

Second, for certain non-emergency services, the law similarly prohibits out-of-network providers from balance billing beyond the patient's in-network obligations, but with an exception that allows some providers to balance bill if they give the patient written notice at least 72 hours before services are provided and obtain the patient's consent.

The 72-hour notice must comply with specific requirements. For example, it must disclose to the patient that the provider is out-of-network, give the patient a good-faith estimate of the out-of-network charges that will be incurred, and identify alternative providers who are available to the patient. But this 72-hour notice exception does not apply for certain types of out-of-network services provided at in-network facilities, including ancillary services (such as anesthesia), diagnostic services (such as radiology and lab), or any other services that the Secretary of Health and Human Services (HHS) may identify. Providers who violate the law's balance billing prohibitions face penalties from HHS of up to $10,000 per violation.

Beyond protecting patients, the Act also provides a framework for resolving certain billing disputes between out-of-network providers and health plans. Under the new federal law, within 30 days of being billed, private health plans that cover emergency services must pay at least a portion of an out-of-network provider's charges for covered emergency services, regardless of whether prior authorization was obtained. The same is true for out-of-network charges for covered non-emergency services rendered at in-network hospitals and facilities. The specific amounts that health plans must pay to out-of-network providers within this 30-day period will generally be determined based on the health plan's median in-network payment for the same or similar services. If the health plan's language excludes or otherwise does not cover the services being provided, then rather than make this partial payment, the health plan may issue a benefit denial within 30 days of being billed for the services.

Upon receiving the health plan's partial payment or denial letter, an out-of-network provider and health plan have 30 days to try to negotiate a resolution of any dispute. If the dispute is not resolved within this timeframe, the provider then has a tight window—four calendar days from the end of the 30-day negotiation period—to initiate an appeal using an Independent Dispute Resolution (IDR) process established under the new federal law.

The IDR process creates an independent review and expedited arbitration process. Within three days of initiating the IDR process, the parties must select a certified IDR entity to decide their dispute. Then, within 10 days of selecting the IDR entity, both the provider and the health plan must submit "final offers" to the IDR entity, together with any supporting materials that the IDR entity requires and any other information either party believes is pertinent to their dispute. The IDR entity will then select one of the two offers. The party

whose offer is not selected must pay the costs of the IDR, which are expected to range from approximately $500 to $2,000 in most cases. Once an IDR entity makes its decision, the balance due must be paid within 30 days.

When deciding which “final offer” to accept, the IDR entity must consider a benchmark known as the “qualifying payment amount” (QPA) for the services at issue. As of January 1, 2022, the QPAs for various services are expected to be set at amounts that represent the median of the contracted (in-network) rates that the health plan paid for such services in the relevant market as of January 31, 2019, with an upward adjustment based on the consumer price index for urban consumers (CPIU). For 2023 and subsequent years, the QPAs for existing health plans will continue to be adjusted upward based on the CPIU. For new health plans formed after January 31, 2019, the QPAs may be calculated based on a different methodology approved by HHS, or pursuant to a database that HHS may set up in accordance with the Act.

The law mandates that an IDR entity consider the QPA when evaluating and deciding which of the competing “final offers” to approve. But there are other factors that IDR entities are also directed to consider, including the provider’s training, experience and outcome measurements; the complexity of the case; the provider’s teaching status; and any contracting rate history between the parties over the prior four years.

Finally, the Act requires that, effective January 1, 2022, providers must have processes in place to ensure they are regularly supplying updated provider information to health plans for use in directories that are made available to help patients identify in-network providers.

For additional information about the requirements of the federal No Surprises Act, please contact Doug Dehler by phone at (414) 276-5000 or by email at doug.dehler@wilaw.com.

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## HEALTH CARE LAW ADVISOR ALERT: DID THE UNITED STATES SUPREME COURT JUST SUGGEST A CHANGE TO THE ESTABLISHED PUBLIC HEALTH CONSTITUTIONAL FRAMEWORK?

American law long has recognized the authority of government officials to address public health emergencies. Almost 200 years ago, the U.S. Supreme Court ruled that, under the 10th Amendment to the U.S. Constitution, the power to address public health emergencies generally is held by the states rather than the federal government. *See Gibbons v. Ogden*, 22 U.S. 1, 205 (1824) (recognizing the "power of a State, to provide for the health of its citizens"). And more than a century ago, the U.S. Supreme Court decided the seminal case on the power of the states to respond to a public health crisis in *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905). There, the Court affirmed the constitutionality of a state statute authorizing local health boards to require that residents be vaccinated against smallpox or pay a five-dollar fine.

As the Court explained in *Jacobson*, the authority to respond to a public health crisis must be "lodged somewhere," and it is "not an unusual, nor an unreasonable or arbitrary, requirement," to vest that authority in officials "appointed, presumably, because of their fitness to determine such questions." *Id.* at 27. The Court intermittently emphasized the necessity of the state public health regulation, as well as the utilitarian aspect of rules protecting the many at the expense of the few, but ultimately seemed to rely on the basic police power of the state to regulate public health as the basis for its decision. *Id.* at 26, 28, 29, 31. Thus, while the *Jacobson* decision shows the high level of deference courts may give to the actions of states faced with a public health crisis, it does not set forth a clear framework for today's courts or governmental officials, in part because the decision arose before the development of modern due process jurisprudence.

In its recent decision in *Roman Catholic Diocese of Brooklyn v. Cuomo*, 592 U.S. ___, 141 S. Ct. 63 (2020), the U.S. Supreme Court may have begun to minimize the impact of *Jacobson today*. There, the Court enjoined an executive order by New York's governor establishing certain occupancy limits to combat the spread of COVID-19. The Court noted that although "[m]embers of this Court are not public health experts, and we should respect the judgment of those with special expertise and responsibility in this area … even in a pandemic, the Constitution cannot be put away and forgotten." *Id.* at *3.

In a concurrence, Justice Neil Gorsuch distinguished *Jacobson from the case before the Court*, stating it "hardly supports cutting the Constitution loose during a pandemic." *Id.* at *5 (Gorsuch, J., concurring). He noted that people affected by the mandatory vaccination order at issue in *Jacobson* could avoid taking the smallpox vaccine by paying a small fine or identifying a basis for exemption and stated that *Jacobson*'s imposition on individual rights therefore was "avoidable and relatively modest" and "easily survived rational basis review,

and might even have survived strict scrutiny, given the opt-outs available to certain objectors." *Id.* at *6. He concluded by calling *Jacobson* a "modest decision." *Id.*

On the other hand, Chief Justice John Roberts quoted a line from *Jacobson* in his dissent, stating that "[o]ur Constitution principally entrusts '[t]he safety and the health of the people' to the politically accountable officials of the States 'to guard and protect.'" *Id.* at *9 (Roberts, C.J., dissenting) (quoting *Jacobson*, 197 U.S. at 38). He concluded that "it is not clear which part of this … quotation today's concurrence finds so discomforting." *Id.*

*Jacobson* and the cases that followed it analyzing past public health emergencies continue to provide guidance today about how to administer public health measures to combat contagious diseases, including current COVID-19 programs. This established law has guided government officials, public health experts, physicians, the public, attorneys and the courts for over a century. But the SARS-CoV-2 virus that causes COVID-19 (and the vaccines and treatments for it) are new. The novel nature of COVID-19, as well as the significant advances in medicine and science since the *Jacobson* decision was issued over a century ago, may lead to new and differing public health jurisprudence governing public health measures to combat the spread of disease. While the recent discussion of the limits of public health authority found in the *Roman Catholic Diocese* does not change established public health precedent, the comments made in the decision suggest the Court may be open to some sort of change in the law in the future.

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# HEALTH CARE LAW ADVISOR ALERT: CORPORATE PRACTICE OF MEDICINE AND FEE SPLITTING–CONSIDERATIONS FOR TELEHEALTH VENTURES

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The increase in the use of telemedicine during the COVID-19 pandemic has given rise to new business ventures among medical practices, technology companies and sometimes also venture capitalists. The relationship between and among the medical practice, the technology component and the financiers must be carefully structured to comply with federal and state law. If structured appropriately, licensed medical providers can be relieved of business administrative functions and instead focus on clinical care. Core legal doctrines driving the business structure of health care ventures include: (1) the corporate practice of medicine (the "CPOM") doctrine; (2) illegal fee splitting laws; and (3) federal and state physician self-referral and anti-kickback statutes. This article focuses on the implications of the CPOM and fee splitting doctrines on medical services and health care technology ventures.

## Corporate Practice of Medicine

The CPOM doctrine prohibits corporations from practicing medicine or employing a physician to provide medical services. *See* WIS. STAT. §448.03(1) (requiring a license to practice medicine); WIS. STAT. § 448.08(1m) (prohibiting fee splitting with non-physicians). The rationale for the CPOM doctrine is that unlicensed entities are not bound by the ethical rules that govern the quality of care delivered by a physician to a patient. Wisconsin's CPOM doctrine is derived not only from the Wisconsin Medical Practices Act, but also from guidance established in Wisconsin Attorney General Opinions.[1] With respect to legally permissible forms of organization for medical providers, the Wisconsin Statutes expressly permit Wisconsin-licensed health care professionals (including, but not limited, to physicians, chiropractors, dentists, podiatrists, optometrists, nurses, pharmacists, and psychologists) to organize themselves and be co-owners in a service corporation and to organize as a professional partnership. *See* WIS. STAT. § 180.1901. Those health care providers whose professional negligence is covered by the Injured Patient and Families Compensation Fund might also organize as a limited liability company ("LLC") with minimal risk of compliance issues, although the law is less clear with respect to LLCs than with service corporations and professional partnerships.[2]

Failure to comply with CPOM and related fee splitting laws can have meaningful implications, such as: (i) physician licensure action or revocation; (ii) liability of non-physician business partners for engaging in medical practice without a license; (iii) voiding of an underlying business arrangement for illegality; and (iv) recoupment of reimbursement payments by commercial or government insurers.[3] A violation of Wisconsin Medical Practice Act requirements may result in a fine of not more than $10,000 or imprisonment for not more than nine months, or for physicians specifically, a fine of not more than $25,000, with certain narrow exceptions. *See* WIS. STAT. § 448.09(1)-(1m).

Which jurisdiction's CPOM doctrine applies to a health care venture depends upon where the patients are located, which can be expansive if telemedicine is involved. Since telemedicine

is frequently practiced across state lines, physician groups and telehealth businesses must structure their operations to account for the variability of the CPOM and fee splitting doctrines (and the degree of enforcement thereof) among jurisdictions. For example, New York's CPOM doctrine and related enforcement is strong comparative to Wisconsin law.[4]

## Management Services Organizations

Compliance with the CPOM and fee-splitting doctrines becomes more complex when clinical telemedicine or medical technology businesses require equity financing from non-licensed investors.[5] A joint venture for telemedicine services may comply with CPOM and related laws by directing the investment by non-licensed persons or entities into a separate state-approved legal entity, often called a management services organization ("MSO"), that would provide non-clinical, administrative support services to physician group practices and other health care providers. The MSO would be compensated for any business and administrative services provided to the legally separate medical practice, excluding revenue earned directly from professional services fees. MSO support services can include areas such as: (i) financial management, budgeting and accounting services; (ii) information technology (IT) services; (iii) human resources and non-clinical personnel management; (iv) coding, billing and collection services; (v) providing and managing office space[6]; (vi) credentialing and contract management; (vii) vendor management and group purchasing; and (viii) marketing services.

In many jurisdictions, central to the analysis of compliance with the CPOM doctrine is the degree of control that the MSO exercises over the operation of the medical practice and/or the professional judgment of licensed health care professionals.[7] Note that even a high level of control over *business* decisions may be suspect in certain jurisdictions.[8] In Illinois, a direct correlation between the fee earned by the clinical practice and the amount paid to the MSO has been found to violate the CPOM laws in addition to the state's fee splitting statutes.[9] Because a MSO's degree of control over a medical practice may be effectuated by a confluence of multiple factors, and will ultimately be judged against a body of law which varies by jurisdiction (*i.e.,* where patients are located during treatment), all MSO arrangements should be evaluated by legal counsel for compliance purposes.

## Fee Splitting Prohibitions

In addition to CPOM concerns, the compensation arrangement between the physician practice and the MSO must be structured to avoid state prohibitions against fee splitting with non-licensed persons or entities. Wisconsin's statutory fee splitting provision prohibits physicians from giving or receiving (directly or indirectly) any form of compensation or anything of value to a person, firm or corporation for inducing or referring a person to communicate with a licensee in a professional capacity or for professional services that were not personally rendered or at the direction of the other licensed professional. [10] *See* WIS.

STAT. § 448.08(1m).

Fee splitting case law varies significantly based upon the law of the local jurisdiction, the specific types of business services provided by the MSO (*e.g.*, leasing of space and equipment, marketing, billing or other business and administrative services), and the compensation structure outlined in the management services agreement.[11] A threshold consideration is whether applicable state law permits fees paid to the MSO that are based upon a percentage of revenue earned from professional services. Some state fee splitting laws permit compensation based upon a percentage of revenue, so long as the consideration is commensurate with the value of services furnished.[12] On the other end of the spectrum, Illinois essentially views any percentage relationship with a physician or professional service corporation as a violation of fee splitting.[13] Additionally, if a MSO generates business or referrals for a medical services entity through marketing or similar services, and under the compensation structure provided by the management services agreement the MSO's marketing services ultimately increase the MSO's revenue stream from the medical services entity, then a management services arrangement is more likely to be scrutinized for illegality in states which enforce fee splitting prohibitions.[14]

In summary, if a telehealth business model depends directly or indirectly on revenues generated from physician services, rather than a technology license, legal analysis for compliance with the CPOM and fee splitting laws is advisable. In addition to legal counsel, a valuation expert should be consulted to ensure that the compensation paid to the non-licensed MSO under the management services agreement reflect the value of each of the various services actually provided by the MSO, rather than increased business volume or referrals.

Irrespective of whether telehealth services will be provided in jurisdictions where CPOM and/or fee splitting laws are strong (or strongly enforced), health care companies should note that the federal Stark or anti-kickback statutes could be implicated if an MSO is deemed to be referring business to the professional services corporation and fee is viewed as compensation for referrals.[15] Recent changes to the federal Stark and anti-kickback laws should generally benefit telehealth and remote patient monitoring; however, experienced legal counsel should be consulted regarding the impact of such fraud and abuse laws on the business arrangement.[16]

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[1] *See* WIS. STAT. § 448.03(1) (requiring licensure by the Medical Examining Board to "practice medicine and surgery, or attempt to do so or make a representation as authorized

to do so"); WIS. STAT. § 448.08(1m) (fee splitting prohibition). See also 71 Op. Att'y Gen. 108 (1982); 75 Op. Att'y Gen. 200 (1986) (widely criticized and ignored on certain grounds discussed herein).

[2] The Wisconsin Department of Regulation and Licensing, which was disbanded in 2011 and replaced by the Department of Safety and Professional Services ("DSPS"), had for years published frequently asked questions ("FAQ") guidance on its website that prohibited physicians from practicing medicine under an LLC or limited liability partnership ("LLP") form of business. The FAQ was based upon an AG opinion, 75 Op. Att'y Gen. 200 (1986), holding that physicians may not organize as business corporations, but note that LLCs and LLPs did not exist at the time of the AG opinion. This FAQ has been removed, as well as a subsequent FAQ that expressly stated that two or more physicians may enter into either partnerships or service corporations. *See* ANDREW G. JACK ET AL, AMERICAN HEALTH LAWYERS ASSOCIATION, CORPORATE PRACTICE OF MEDICINE: A 50-STATE SURVEY 570(2nd ed. 2020). The rationale for the 1986 AG opinion was that business corporations afforded broad limited liability for their members (no carve out for a member's own professional negligence, as is the case for a service corporation or general partnership). See Adam J. Tutaj, Wisconsin's Corporate Practice of Medicine Doctrine: Dead Letter, Trap for the Unwary, or Both?, STATE BAR OF WIS. PINNACLE, TRACK 3, SESSION 4 (Dec. 2019). In view of the current ambiguity under Wisconsin law with respect to LLCs, any two more medical professionals seeking to organize as an LLC confirm that patients can in fact be compensated for professional negligence by coverage by the Injured Patient and Families Compensation Fund for the area of medical practice at issue.

[3] *See generally* JACK ET AL., *supra* note 2.

[4] *See id*.

[5] Under Wisconsin law, the term "person" (required to obtain a license issued by the Medical Examining Board) extends to partnerships, associations, and corporations. See Wis. Stat. § 990.01(26). *See also* WIS. STAT. § 448.03(1).

[6] Whether a lease agreement between an MSO and a service provider entity is legal often depends upon whether the relationship between lessor and lessee involves referrals. See JACK ET AL., *supra* note 2, at 136-37 (comparing *The Petition for Declaratory Statement of Melbourne Health Associates, Inc. and John Lozito, M.D.*, 9 FALR 6295 (1987), with *The Petition for Declaratory Statement of Joseph M. Zeterberg, M.D.*, 12 FALR 1036 (1990)).

[7] *See* e.g., 83 Op. Cal. Atty. Gen. 170 (July 27, 2000) (emphasizing the impossibility of distinguishing between professional and non-professional services when scrutinizing an arrangement between an MSO and a union whereby the MSO selected the radiology site and radiologist and paid for radiology diagnostic services for union members in exchange for a

fee that included both the gross amount for professional services and the MSO's compensation); JACK ET AL., *supra* note 2, at 69.

[8] *See* e.g., *Andrew Carothers, M.D., P.C. v. Progressive Ins. Co.*, 2019 N.Y. Slip Op. 04643 (June 11, 2019). The New York Court of Appeals held that medical practices that give too much operational and financial control to MSOs are "fraudulently incorporated," and not entitled to reimbursement by no-fault auto insurers. See id. (cited by JACK ET AL., *supra* note 2, at 365-66).

[9] *See TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II*, Ltd., 714 N.E.2d 45 (Ill. App. Ct. 1999) (concluding that where a service agreement provided for an annual fee to be paid to an unlicensed corporation, the arrangement illegally violated the corporate practice of medicine doctrine even where the fee was not a straight percentage, because there was a relationship between the amount of revenue earned and the fee paid).

[10] The Wisconsin Attorney General has issued an opinion that addresses fee splitting. See 71 Op. Att'y Gen. 108, 109 (1982) (asserting that the statutory prohibition against fee splitting was aimed at addressing "fees or commissions [that] were not for any services rendered to the patient, but purely a service rendered to the other physicians or surgeons in the way of sending them this business.")

[11] *See e.g., The Petition for Declaratory Statement of Edmund G. Lundy, M.D.*, 9 FALR 6289 (1987) (emphasizing the state statute's emphasis on prohibited *referrals* when finding no violation of the Florida fee-splitting prohibition under circumstances where a business entity provided office space, equipment, advertising and billing services to family practitioners in exchange for 40% of their respective collections) (cited in Jack et al., *supra* note 2, at 136); *TLC The Laser Ctr., Inc. v. Midwest Eye Inst. II*, Ltd., 714 N.E.2d 45, 56 (Ill. App. Ct. 1999) (finding that where a service agreement provided for an annual fee to be paid to an unlicensed corporation, the arrangement illegally violated the statutory prohibition against fee splitting, even where the fee was not a straight percentage, because "the fee clearly increased as revenues increased"); *Vine Street Clinic v. HealthLink, Inc.*, 856 N.E.2d 422, 434 (Ill. 2006) (holding that a corporation that creates a network of health care providers may receive a flat fee for administrative services, but not a percentage fee, for services rendered). The Illinois Supreme Court reasoned that the flat fee did not implicate public policy concerns because the "flat fee is charged to each participating physician for administrative services rendered, not for referrals, and thus no 'recommendation' component exists." *Id*. at 435. Central to the court's ruling was the fact that the flat fee would not affect the treatment given to the patient. See JACK ET AL., *supra* note 2, at 168-69. See also *Ashley MRI Mgt. Corp. v. Perkes*, No. 001915-05, 2010 WL 441941(N.Y. Sup. Ct. Jan. 26, 2010). In this case, the court raised significant issues regarding a management relationship under which the non-licensed professional manager received a percentage of the "net revenue" earned by licensed health care professionals in connection with the subleasing of an MRI facility,

concluding that such an arrangement "may be an illegal fee splitting arrangement." *Id*. The court in Ashley Management also questioned as a potentially illegal fee splitting arrangement an arrangement whereby one of the unlicensed business entities involved received a flat usage fee for each MRI or diagnostic scan performed by the licensed health professionals. The court explained that the direct sharing of radiology fees with a non-physician raises public policy concerns as to the quality of care and the corporate practice of medicine. See JACK ET AL., *supra* note 2, at 364.

[12] *See* e.g., California Business & Professions Code §650(b); *Epic Med. Mgmt., LLC v. Paquette*, 198 Cal.Rptr.3d 28 (Cal. Ct. App. 2015) (relying on §650(b) in a case in which the management company actually charged a fee equal to 50% of the revenue for office medical services, 25% of the revenue for surgical services and 75% of the revenue of pharmaceutical-related revenues) (cited in JACK ET AL., supra note 2, at 66).

[13] Illinois's Medical Practice Act prohibits direct or indirect payment of a percentage of the licensee's professional fees, revenues or profits to anyone for negotiating fees, charges or terms of service or payment on behalf of the licensee, among numerous other prohibited services. See 225 Ill. Comp. Stat. 60/22.2. The Illinois Medical Practice Act includes several exceptions, including paying fair market value for billing, administrative assistance or collection services. See JACK ET AL., *supra* note 2, at 165-66.

[14] *See* JACK ET AL., supra note 2, at 136-138, 168-69 (summarizing key Florida and Illinois case law defining each state's fee splitting prohibition and emphasizing the courts' concern with payments for developing affiliations with local clinical practices, marketing services and "practice expansion" services, as well as incentives to add patients to a practice, respectively) (citing *The Petition for Declaratory Statement of Joseph M. Zeterberg*, M.D. 12 FALR 1036 (1990); *The Petition for Declaratory Statement of Magan Bakarania, M.D.*, Final Order Issued October 17, 1997; *The Petition for Declaratory Statement of Dr. Gary Johnson, M.D. and The Green Clinic*, 14 FALR 3936 (November 30, 1990); *The Petition for Declaratory Statement of Rew, Rogers and Silver, M.D.'s, P.A.*, 12 FALR 4139, Final Order issued August 25, 1999; *Gold, Vann & White, P.A. v. Friedenstab*, 831 So. 2d 692 (Dist. Ct. App. 2002). *See also E&B Mktg. Enter., Inc. v. Ryan*, 568 N.E.2d 339, 341-42 (Ill. App. Ct. 1991) (determining that an illegal fee splitting arrangement existed under Illinois law where the plaintiff was to receive a fee of 10% of all billings collected by the doctor in exchange for the plaintiff's advertising, which primarily targeted insurance companies); *Vine Street Clinic v. HealthLink, Inc.*, 856 N.E.2d 422 (Ill. 2006) (emphasizing that a flat service fee for administrative services reflected compensation for services actually rendered rather than compensation for referrals).

[15] *See* 42 U.S.C. §1395nn (Physician Self-Referral, or Stark law); 42 U.S.C. §1320a-7b(b) (Anti-Kickback statute). Note that health care ventures must also comply with state health care fraud and abuse statutes.

[16] *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020) (to be codified at 42 CFR pts. 1001, 1003), available at https://www.federalregister.gov/public-inspection/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the (last accessed Feb. 22, 2021); Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020) (to be codified at 42 C.F.R. pt. 411), available at https://www.federalregister.gov/public-inspection/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations (last accessed Feb. 22, 2021).

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# HEALTH CARE LAW ADVISOR ALERT: VACCINE INJURY CLAIMS AND THE FEDERAL VACCINE COURT

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As the development of a potential COVID-19 vaccine continues, so too do questions about the types of vaccines being developed and how they will be administered. Vaccines offer overwhelming public health benefits, but a small number of individuals who receive vaccines are harmed by them. Most claims alleging health problems caused by vaccines must be brought in the "Vaccine Court" of the United States Court of Federal Claims under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1, *et seq*.

The Act creates the National Vaccine Injury Compensation Program to handle vaccine-related claims. The program is administered by a secretary who may compensate a party who has suffered a vaccine-related injury or death. The Act largely preempts traditional tort claims against vaccine administrators or manufacturers for vaccine-related injuries and it limits claimants to only those sustaining injury or their legal representatives.

The Act creates a Vaccine Injury Table listing various vaccines and medical conditions that may result from them. Claimants must show, by a preponderance of evidence, that they suffered an injury listed in the Table or that a vaccine caused or significantly aggravated their injury within the time periods set forth in the Table. *Terran ex rel. Terran v. Sec'y of Health and Human Servs.,* 195 F.3d 1302, 1307 (Fed. Cir. 1999), *cert. denied,* 531 U.S. 812 (2000). If

claimants do so for an injury listed in the Table within the time period stated in the Table, they are presumed to be entitled to compensation. *Knutson by Knutson v. Sec'y of Health and Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994). For claims not falling within the Table, claimants must prove the vaccine at issue caused their injury by a preponderance of evidence. *Golub v. Sec'y of Health and Human Servs.*, No. 99-5161, 2000 WL 1471643, at *2 (Fed. Cir. Oct. 3, 2000). Claimants are limited to a recovery of $250,000 for pain and suffering, but may recover additional damages for actual and projected un-reimbursable expenses, actual and anticipated lost earnings, and reasonable attorneys' fees and costs.

Claims made to the Vaccine Court are sent to the office of the Chief Special Master, who then assigns the claim to a special master to review and issue a decision to be entered as a judgment by the Federal Court of Claims. Either party can request that the Federal Court of Claims review this decision, and also can seek further review in the United States Court of Appeals for the Federal Circuit. Judicial review of the special masters' decision is limited; the decision can be set aside only if either court determines it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. If claimants choose to reject a judgment by the Vaccine Court, they then may pursue a tort action in state or federal court. However, the Act offers certain defenses and presumptions to defendants facing such claims.

For more information about the Vaccine Court, or other legal issues relating to the COVID-19 pandemic, contact Grant Killoran of O'Neil, Cannon, Hollman, DeJong & Laing S.C. at 414-276-5000 or grant.killoran@wilaw.com.

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# HEALTH CARE LAW ADVISOR ALERT: TELEHEALTH IN WISCONSIN (PART 2 OF 2)

O'NEILCANNON
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## Medical Malpractice Risk & Telemedicine Policies

This article is the second of a two-part series on telehealth in Wisconsin. The first article of this series, available here, highlighted basic standards for regulatory compliance in the design of internal telehealth policies. This second article addresses the practitioner's obligation to minimize patient harm (and thus practitioner liability) with attention to the

medical standard of care when assessing when and how telehealth is appropriate for each patient.

## A. Maintaining Medical Standard of Care in Telemedicine

Wisconsin medical providers must critically evaluate whether their use of a telemedicine platform would permit their evaluation and treatment of each patient in compliance with "the standard of minimally competent medical practice."[i] Standards of practice and conduct required for in-person visits, including standards relating to patient confidentiality and recordkeeping, must be observed in the telehealth context.[ii]

In view of these standards articulated by the Wisconsin medical examining board, internal telemedicine policies and procedures must preserve the same degree of quality and safety achieved during in person appointments. Clinical leadership must assess whether quality of patient care can be maintained via telehealth, an evaluation which is dependent upon the provider's area of specialty, the patient's condition, and other factors. For example, the use of telemedicine is not suitable for conditions where physical examinations are necessary, because of extreme symptoms, forceful interventions, or in the case of medical procedures for which certain protocols need to be followed.[iii]

Clinical guidelines specific to telemedicine can serve as important indicators as to whether your practice should incorporate telemedicine for specific patient encounters or diagnostic evaluations.[iv] However, guideline compliance does not guarantee accurate diagnosis or safe and effective medical care meeting the standard of care. Local circumstances must be considered, and the practitioner is ultimately responsible for all decisions regarding the appropriateness of a specific course of action.[v] Published guidelines for every clinical scenario and application simply do not exist and so by necessity may need to be developed in-house.[vi] The policies of each medical practice should delineate between circumstances in which various telehealth platforms can, and cannot, preserve the quality of care for patients. Providing treatment recommendations, including issuing a prescription, based only on a static electronic questionnaire does not meet the standard of minimally competent medical practice.[vii]

Sometimes the proper standard of care is reflected in government reimbursement decisions. For example, the Wisconsin Department of Health Services' ("DHS") expansion of telehealth coverage will exclude comprehensive assessment and care planning for children with complexities, since this requires an in-person assessment. However, case management for children with complex medical needs will be covered. Certain, but not all, dental evaluations will be covered. Certain therapy services will be covered.[viii]

Where clinical leadership determines that telehealth is appropriate, workflow must be re-evaluated in the telehealth context to maintain the standard of care. For example, staff

responsibilities may require adjustment for telehealth encounters to ensure that updates to the medical record, physician orders and the "after visit summary" are properly recorded in connection with each telehealth encounter. Providers may consider requiring immediate scheduling of patients who express symptoms that require in-person evaluation during a telemedicine visit to promote patient safety and minimize liability. Providers might also consider whether patient/family coaching regarding medication administration is properly handled in the telehealth context.

## B. Telephone and Texting: Risk Mitigation

While the use of synchronous audio and video visits has exploded in the wake of the COVID-19 pandemic, physicians have provided routine medical advice by phone for decades, responding to patient calls reporting a change in condition and advising medication changes by phone communications. Surveys of patients since the COVID-19 pandemic indicates that texting is a preferred method of communication over phone calls.[ix] In addition to health care privacy and security issues (outside of the scope of this article), what are some of the legal considerations for such telephone and texting encounters?

First, practitioners must observe the criteria for government and private insurer reimbursement of telehealth, unless their practice is limited to self-pay. In the case of Medicaid reimbursement, the Wisconsin Medical Assistance Program generally covers consultations through "interactive telehealth" and certain asynchronous telehealth services and remote patient monitoring.[x] The Wisconsin Statutes delegate authority to DHS to determine whether to include telephone encounters within the definition of "telehealth."[xi] DHS is temporarily providing coverage for certain telephone visits during COVID-19 pandemic, and the agency may ultimately decide to continue coverage of certain telephone communications as part of its permanent policy.[xii] Audio-only telephone communications must be delivered with the functional equivalency of a face-to-face encounter in order to be covered by Wisconsin Medicaid during the COVID-19 pandemic.[xiii]

If the patient will be located out-of-state, the provider must assess whether the applicable state's criteria for Medicaid telehealth reimbursement differs from the requirements imposed by Wisconsin Medicaid.[xiv] If federal Medicare will instead serve as payor, the Centers for Medicare and Medicaid Services ("CMS") will reimburse certain audio-only phone visits during the COVID-19 public health emergency. For reimbursement purposes, CMS distinguishes "telephone visits" from "services that "would normally occur in person." Telephone visits are "not paid as though the service occurred in person," and reimbursement may be bundled into a pre- or post-service if the phone encounter falls within the previous seven days of a prior visit or leads to a subsequent evaluation/management service.[xv]

Because audio-only telephone and texting encounters are inherently more limited with respect to patient evaluation capabilities, providers should exercise caution when using these

modes of telehealth in circumstances that would usually *or could* warrant a physical evaluation of the patient based upon medical history or the symptoms described when scheduling an appointment. In addition to introducing risk of medical malpractice claims, providers risk non-compliance with criteria for reimbursement, such the standard of "functional equivalency to the face-to-face service" required by state Medicaid for reimbursement. The "functional equivalency standard" applicable to state government reimbursement is higher than the "the standard of minimally competent medical practice" generally applicable to the practice of telemedicine in the state.[xvi]

## C. Updates to Telehealth Policies and Procedures

Irrespective of whether government reimbursement is in play, your medical practice policies and procedures should be updated to mitigate risk to patient care and safety in the telehealth context. Your internal policies and procedures should delineate between when telemedicine is (and is not) appropriate based upon a critical assessment of each of the several evaluative and diagnostic services provided by your practice. Staff, including schedulers and nurses, should be trained as to when scheduling a telemedicine appointment poses risk to your patients and your practice. Your policies should incorporate customized procedures designed to preserve the standard of care and the medical recordkeeping requirements imposed by the Wisconsin medical examining board for the practice of telemedicine. In addition, physicians practicing telemedicine should confirm that their medical malpractice insurance coverage applies outside of the traditional health care facility settings.

OCHDL's health care practice group will continue to monitor telehealth regulations and related guidance as the standard of care for telemedicine evolves. For more information on this topic, contact Marguerite Hammes at 414-276-5000 or marguerite.hammes@wilaw.com.

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**[i]** ***See*** **WIS. ADMIN. CODE § MED 24.06.**

**[ii]** ***See*** **WIS. ADMIN. CODE § MED 24.05. (requiring the same standard of practice and conduct regardless of whether health care services are provided in person or by telemedicine). The standard of care that is required of all Wisconsin health care providers is defined as the degree of skill, care, and judgment which reasonable health care providers who practice the same specialty would exercise in the same or similar circumstances, having due regard for the state of medical science at the time.** ***Nowatske v. Osterloh*****, 198 Wis.2d 419, 543 N.W.2d 25 (1996),** ***abrogated on other ground by Nommensen v. American Continental Ins. Co.*****, 246 Wis.2nd 132, 629 N.W.2d 132 (2001); Wis. J.I. Civil No. 1023.**

**[iii] Secure Medical, Best Telemedicine Clinical Guidelines (April 13, 2018), available at https://www.securemedical.com/telemedicine/best-telemedicine-clinical-guidelines/**

[iv] ***E.g.,*** **American Telemedicine Association, Practice Guidelines Archives, available at https://www.americantelemed.org/resource_categories/practice-guidelines/ ; Pantanowitz, Liron et al. "American Telemedicine Association clinical guidelines for telepathology." Journal of pathology informatics vol. 5,1 39. 21 Oct. 2014, doi:10.4103/2153-3539.143329; Krupinski, Elizabeth A, and Jordana Bernard. "Standards and Guidelines in Telemedicine and Telehealth." Healthcare (Basel, Switzerland) vol. 2,1 74-93. 12 Feb. 2014, doi:10.3390/healthcare2010074.**

[v] **Elizabeth A. Krupinski and Jordana Bernard, Standards and Guidelines in Telemedicine and Telehealth, Healthcare 2014, 2, 74-93; doi: 10.3390/healthcare2010074, at 81.**

[vi] ***See*** **Standards and Guidelines in Telemedicine and Telehealth, Healthcare, supra note 5, at 81.**

[vii] ***See*** **WIS. ADMIN. CODE § MED 24.07 (2).**

[viii] ***See*** **Brook Anderson, Wisconsin DHS Benefits Policy Section Chief, Telehealth Expansion: Acute and Primary Services, available at https://www.dhs.wisconsin.gov/telehealth/telehealth-expansion-all-provider.pdf (revised July 30, 2020).**

[ix] **SR Heath, Patient Communication Preferences: the COVID-19 Impact, July 30, 2020, available at https://mhealthintelligence.com/resources/white-papers/patient-communication-preferences-the-covid-19-impact eid=CXTEL000000554482&elqCampaignId=16139&utm_source=ded&utm_medium=email&utm_campaign=dedicated&elqTrackId=607a1670c3c349349ac195f03c60cba2&elq=362f09f490fe41169f2fc16dbcab5410&elqaid=16904&elqat=1&elqCampaignId=16139**

[x] ***See*** **WIS. STAT. § 49.46(2)(b)(21)-(22).**

[xi] ***See*** **WIS. STAT. § 49.45(61)(a)(4); §49.46(2)(b)(23).**

[xii] ***See*** **ForwardHealth Update 2020-12, "Temporary Changes to Telehealth Policy and Clarifications for Behavioral Health and Targeted Case Management Providers" (revised May 8, 2020), available at https://www.forwardhealth.wi.gov/kw/pdf/2020-12.pdf**

[xiii] ***See id*.**

[xiv] ***See*** **Center For Connected Health Policy, State Telehealth Laws & Reimbursement Policies (Fall 2020), available at https://www.cchpca.org/sites/default/files/2020-10/CCHP%2050%20STATE%20REPORT%20FALL%202020%20FINAL.pdf**

[xv] ***See, e.g.,*** **Centers for Medicare and Medicaid Services, COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing (revised October 20, 2020), at 63-79, available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf**

[xvi] ***Compare*** **Wisconsin ForwardHealth Telehealth Expansion and Related Resources for Providers, available at https://www.forwardhealth.wi.gov/WIPortal/content/html/news/telehealth_resources.html.spage , *with* WIS. ADMIN. CODE § MED 24.06.**

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# HEALTH CARE LAW ADVISOR ALERT:

# TELEHEALTH IN WISCONSIN (PART 1 OF 2)

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## I. Expansion of Telehealth to Meet Clinical Need

Federal and state governments have resolved traditional barriers to telehealth – including complexity of billing, lower reimbursement and privacy and security concerns – to facilitate the safe provision of medical services during the COVID-19 pandemic.[i] The first article in this two-part series highlights basic standards for regulatory compliance in the design of telehealth policies. The second article will address the practitioner's obligation to minimize patient harm (and thus practitioner liability) with attention to the medical standard of care when assessing when and how telehealth is appropriate for each patient.

## II. Mechanics of Telehealth Compliance

### A. Minimum Standards for Telehealth Practice

A Wisconsin physician planning to provide treatment recommendations (including a prescription) by use of a website-based platform must observe requirements promulgated by the Wisconsin medical examining board to comply with state law and (when applicable) to receive payment from Wisconsin Medicaid.[ii] While the requirement that the physician be licensed to practice medicine in the state has been suspended during the COVID-19 emergency,[iii] the following formalities must still be observed during the pandemic to protect the integrity of the telemedicine encounter:

1. Physician's name and contact information must be made available to the patient;
2. Informed consent must be obtained;[iv]
3. A documented evaluation (including a medical history) must be performed. If needed to satisfy standards of minimally competent medical practice, an examination, evaluation, and/or diagnostic tests are also required.
4. A patient health care record must be prepared and maintained.[v]

Under permanent Wisconsin telemedicine regulations, a physician-patient relationship may be initially established by use of two-way electronic communications, but not by use of audio-only telephone, email messages or text messages.[vi] Conditioning treatment of a patient upon the use of telehealth is expressly prohibited.[vii]

## B. Reimbursable Telehealth Services

### 1. Wisconsin Medicaid & Telehealth

Wisconsin lawmakers began expanding the services and communications that may be provided by telehealth prior to the COVID-19 pandemic. The Wisconsin Department of Health Services ("DHS") continues to broaden the range of medical services covered by the state's medical assistance program when delivered remotely, both during the public health emergency and beyond.[viii] DHS is adding Medicaid coverage for *currently covered services* when provided using a telehealth platform if *functionally equivalent to an in-person visit* (interactive synchronous technology).[ix] DHS's criteria for "face-to-face equivalence" for interactive telehealth services includes the use of "audio, video, or telecommunication technology," but only if there is "no reduction in quality, safety, or effectiveness."[x] Audio-only phone communication that can be delivered with a functional equivalency to face-to-face service will be covered during the COVID-19 pandemic.[xi] DHS emphasizes that documentation must support the service rendered.[xii] For further explanation of these policies, visit ForwardHealth, Telehealth, Telehealth Expansion and Related Resources for Providers.[xiii]

Telehealth coverage expansion applies to all services currently indicated in topic (#510) of the FowardHealth Online Handbook (permanent policy), and additional services temporarily allowed for telehealth are published in ForwardHealth Updates.[xiv] For example, ForwardHealth is expanding coverage to include certain synchronous (real-time) and asynchronous (not real-time) services such as remote patient monitoring and provider-to-provider consultations. DHS also plans to roll out expansion updates particular to specific services areas, such as therapy and behavioral health. DHS will use a phased approach to its expansion of telehealth services, keeping providers informed of expansion of coverage via the ForwardHealth website described above.

In addition to coverage criteria relating to the mode of telehealth services, a provider must be mindful of rules governing the logistics of telehealth visits. Wisconsin Medical Assistance (Medicaid) places no restriction on the location of the provider (permanent policy), which may include physicians, nurse practitioners, Ph.D. psychologists, psychiatrists and others.[xv] Beginning in March 2020, ForwardHealth began allowing coverage irrespective of the location of the patient (permanent policy).[xvi] However, only the following sites are currently eligible for a facility fee: hospitals, including emergency departments, office/clinics, and skilled nursing facilities.[xvii]

### 2. Federal Medicare & Telehealth

The Centers for Medicare and Medicaid Services ("CMS") greatly expanded access to

Medicare telehealth services based upon the regulatory flexibilities granted under Social Security Act § 1135 waiver authority and the Coronavirus Preparedness and Response Supplemental Appropriations Act. Currently, Medicare will reimburse both synchronous video visits and also brief communication technology-based services ("CTBS") for responses to Medicare Part B beneficiaries by telephone, audio/video, secure text messaging or by use of a patient portal.[xviii] Reimbursement for CTBS is limited to patients with an established (or exiting) relationship with a physician or certain practitioners. The billing codes for CTBS represent ***brief, patient-initiated*** communication services and do not replace full evaluation and treatment services covered under the Medicare benefit and described by existing CPT codes. To meet the criteria for medical necessity, CTBS must require clinical decision-making and not be for administrative or scheduling purposes. The patient must verbally consent to these types of services at least annually.

To be covered by Medicare, the CTBS must not be related to a medical visit within the previous seven (7) days and cannot lead to a medical visit within the next twenty-four (24) hours (or soonest appointment available).[xix] For Medicare reimbursement, providers must confirm that the particular diagnostic benefit falls within the description of CTBS codes. For example, CTBS codes do not include the audiology diagnostic benefit category.[xx] DHS applies similar requirements to billing for "telephone evaluation and management services" covered under Wisconsin Medicare.[xxi]

During the COVID-19 pandemic, Medicare will reimburse telehealth services at the same rate as regular, in-person visits. The level of reimbursement that is approved following the public health emergency will impact the availability of telehealth services.

## C. Documentation Requirements

DHS policy (published via ForwardHealth updates available online) is to require that all services provided via telehealth be thoroughly documented in the member's medical record in the same manner as services provided face-to-face.[xxii] Providers must develop and implement their own methods of informed consent to confirm that a member agrees to receive services via telehealth. ForwardHealth considers verbal consent to receiving services via telehealth an acceptable method of informed consent when it is documented in the member's medical record.[xxiii] Documentation for originating sites (patient location) must support the member's presence in order to submit a claim for the originating site facility fee. In addition, if the originating site provides and bills for services and also the originating site facility fee, documentation in the member's medical record should distinguish between the unique services provided.[xxiv]

DHS is temporarily allowing supervision requirements for paraprofessional providers to be met via telehealth. Supervision must be documented according to existing benefit policy.[xxv]

## III. Additional Considerations for Telehealth

***E-Prescribing*** – Many states limit the prescribing of controlled substances based solely on telehealth examination. Generally speaking, the U.S. Drug Enforcement Administration ("DEA") requires a telemedicine provider to have an in-person medical evaluation of a patient prior to prescribing a controlled substance for the patient, absent an exception. However, the DEA issued notice in March 2020 that this requirement is waived for the duration of the COVID-19 public health emergency.[xxvi]

***Privacy & Security*** – The Office for Civil Rights announced on March 17, 2020 that they will not impose penalties for noncompliance with the Health Insurance Portability and Accountability Act of 1996 regulatory requirements for remote communications technologies in connection with the good faith provision of telehealth during the national COVID-19 public health emergency. DHS has issued an update clarifying guidance regarding federal enforcement of the Health Insurance Portability and Accountability Act of 1996 regulatory requirements during the COVID-19 pandemic.[xxvii]

***Practicing Telehealth Across State Lines* –** Wisconsin has adopted the Federation of State Medical Boards' Interstate Licensure Compact, which aims to expediate physician licenses for uses like telemedicine in states that adopt the compact. Wisconsin providers serving patients in other states must consult local state laws governing the physician-patient relationship and the use of telemedicine.

When a Wisconsin provider provides telemedicine services to a patient located outside of the state, legal review for choice of law and choice of forum should be undertaken. For example, the laws of the state in which each patient is located should be evaluated for: (1) statute of limitations; (2) standard of care; (3) limitations of liability; and (4) unique provisions governing the establishment or termination of the physician/patient relationship. To manage these challenges in a large telemedicine practice, a provider may need to consider establishing different legal entities for the practice of medicine in different states.

OCHDL will continue to monitor changes in regulations and policy impacting telemedicine. Our next blog post will address medical malpractice risk and telemedicine policies. For more information on these topics, contact Marguerite Hammes at 414-276-5000 or marguerite.hammes@wilaw.com.

[i] SR Health, A Complete Guide to Seeing Patients Virtually and Getting Paid for It, available at https://www.srhealth.com/resources/telemedicine-guide

[ii] *See* WIS. ADMIN. CODE § MED 24.07 (1).

[iii] In the ordinary course, a physician practicing telemedicine in Wisconsin must be licensed to practice medicine and surgery by the medical examining board as required by Wis. Admin. Code § MED 24.04. *See* Wis. Admin. Code § MED 24.07 (1). However, Wis. Admin. Code § MED 24.04 (requiring a physician practicing medicine in Wisconsin to be licensed by the medical examining board) and 24.07(1)(a) (applying licensing requirements to medical practice by telemedicine in the state) have been suspended during the COVID-19 emergency. *See* Governor Tony Evers Emergency Order #16 Related to Certain Health Care Providers and the Department of Safety and Professional Services Credentialing, dated March 27, 2020.

[iv] WIS. ADMIN. CODE § MED 24.07 (1) (citing WIS. STAT. § 448.30 and Ch. MED. 18).

[v] WIS. ADMIN. CODE § MED 24.07(1) (citing ch. MED. 21).

[vi] *See id.* § MED 24.03.

[vii] ForwardHealth Update No. 2020-09, "Changes to ForwardHealth Telehealth Policies for Covered Services, Originating Sites, and Federally Qualified Health Centers" (March 18, 2020).

[viii] *See* WIS. STAT. § 49.45(61)(b); § 49.46(2)(b)(21)-(23). DHS is expanding the permanent definition of telehealth to encompass the "practice of health care delivery, diagnosis, consultation, treatment, or transfer of medically relevant data by means of audio, video, or data communications that are used either during a patient visit or consultation or are used to transfer medically relevant data about a patient." *See* ForwardHealth, Telehealth, Telehealth Expansion and Related Resources for Providers, available at https://www.forwardhealth.wi.gov/WIPortal/content/html/news/telehealth_resources.html.spage *See also* Letter to ForwardHealth Providers from Jim Jones, State Medicaid Director, re: Wisconsin Medicaid Response to the COVID-19 Outbreak; FowardHealth #510.

[ix] *See* ForwardHealth Update 2020-09, *supra* note vii (permanent policy); ForwardHealth Update 2020-12, "Temporary Changes to Telehealth Policy and Clarifications for Behavioral Health and Targeted Case Management Providers" (Revised May 8, 2020); ForwardHealth Update 2020-15, "Additional Services to be Provided Via Telehealth" (Revised May 8, 2020) (temporary expansion policy). *See also* Brooke Anderson, Benefits Policy Section Chief, Telehealth Expansion: Acute and Primary Services, available at https://www.dhs.wisconsin.gov/telehealth/telehealth-expansion-all-provider.pdf

[x] *See* ForwardHealth, Telehealth, Telehealth Expansion and Related Resources for Providers, *supra* note viii. *See also* Brooke Anderson, Benefits Policy Section Chief, Telehealth Expansion: Acute and Primary Services, *supra* note ix.

[xi] ForwardHealth Update 2020-12, *supra* note ix.

[xii] ForwardHealth, Telehealth, Telehealth Expansion and Related Resources for Providers, *supra* note viii.

[xiii] For further explanation of these policies, visit ForwardHealth, Telehealth, Telehealth Expansion and Related Resources for Providers, *supra* note viii. *See also* Brooke Anderson, Benefits Policy Section Chief, Telehealth Expansion: Acute and Primary Services, *supra* note ix.

[xiv] ForwardHealth Update 2020-15, *supra* note ix.

[xv] ForwardHealth Update 2020-12, *supra* note ix (permanent policy with respect to provider location but temporary with respect to other policy changes).

[xvi] ForwardHealth Update 2020-09, *supra* note ix (permanent policy changes).

[xvii] **ForwardHealth, Topic 510, Telehealth, available at https://www.forwardhealth.wi.gov/WIPortal/Subsystem/KW/Print.aspx?ia=1&p=1&sa=1&s=2&c=61&nt=Telehealth**

[xviii] **Centers for Medicare and Medicaid Services, Medicare Telemedicine Health Care Provider Fact Sheet, available at https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet**

[xix] ***See id.***

[xx] **American Speech-Language-Hearing Association, Use of Communication Technology-Based Services During Caronavirus/COVID-19 (June 6, 2020), available at https://www.asha.org/Practice/reimbursement/medicare/Use-of-E-Visit-Codes-for-Medicare-Part-B-Services-During-Coronavirus/**

[xxi] **ForwardHealth Update 2020-09, *supra* note vii.**

[xxii] **ForwardHealth Update 2020-12, *supra* note ix (citing Wis. Admin. Code § DHS 106.02(9); ForwardHealth Online Handbook #201 (Financial Records), #202 (Medical Records); #203 (Preparation and Maintenance of Records); #204 (Records Retention); #1640 (Availability of Records to Authorized Personnel)).**

[xxiii] ***See* ForwardHealth Update 2020-15, *supra* note ix.**

[xxiv] ***See* ForwardHealth Update 2020-12, *supra* note ix.**

[xxv] ***See id.***

[xxvi] **DEA Press Release, DEA's Response to COVID-19 (March 20, 2020), available at https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19**

[xxvii] ***See* ForwardHealth Update 2020-12, *supra* note ix.**

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# HEALTH CARE LAW ADVISOR ALERT: VIDEOCONFERENCING CONSIDERATIONS FOR HEALTH CARE LITIGATORS

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These days, litigators are routinely taking depositions and participating in hearings over Zoom or other videoconferencing apps and software. Frequently, these depositions and hearings are set up using videoconferencing systems chosen, hosted, and controlled by a court, an arbitrator, or a court reporter. There has been significant discussion and administrative guidance about the use of videoconferencing by health care providers since

the pandemic began. Health care litigators should also consider the implications of video depositions or hearings on HIPAA security obligations.

Zoom reports that it is HIPAA compliant. However, these features must be requested by the subscriber, typically through a Zoom for Healthcare subscription. Microsoft Teams also reports it is capable of HIPAA compliance, as does Google Meet.

Litigators who anticipate protected health information (PHI) may be discussed or contained in documents shared through a videoconferencing platform for purposes of a deposition or hearing should inquire with the host about the type of subscription and system capabilities. Some court reporters offer special HIPAA-compliant rooms with certain features disabled.

With the rapid transition to videoconferencing to conduct a substantial amount of litigation tasks, guidance in this area is likely to continue to evolve along with videoconferencing system capabilities. Health care providers and their outside litigators should stay informed and be prepared to ask the right questions to ensure they are not overlooking HIPAA obligations.

The attorneys who contribute to the Health Care Law Advisor are available to assist health care providers with a variety of legal matters. Please contact us if you need assistance navigating the pandemic-related changes to health care litigation.

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# HEALTH CARE LAW ADVISOR ALERT: WELL-DRAFTED ASSIGNMENT OF BENEFIT FORMS ARE CRITICAL WHEN FIGHTING ERISA CLAIM DENIALS

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Most private health insurance coverage in the United States is employer-sponsored and governed by a federal law known as the Employment Retirement Income Security Act of 1974 (ERISA). Navigating an appeal of a benefit denial issued by an ERISA-governed health plan can be confusing. A quick review of federal regulations governing ERISA benefit denials, which can be found **here**, suggests how challenging it may be for health care providers to

navigate the ERISA claims landscape successfully.

ERISA benefit denials are frequently written by a health insurer or third-party administrator (TPA) that is not the legal entity truly providing the health benefits to the patient. The legal entity providing the benefits—the health insurer**,** so to speak—is known as an "ERISA plan." When a health care provider obtains an assignment of its patient's benefits, those rights are against the ERISA plan, not necessarily the health insurer or TPA that may have written a benefit denial letter.

Health care providers can improve their chances of successfully recovering benefits from ERISA plans by ensuring that their Assignment of  Benefit (AOB) forms are properly worded. AOB forms should fully authorize a provider to pursue all of its patient's appeal rights under ERISA. In addition, AOB forms should allow a health care provider to obtain full information about the ERISA plan's benefits, so that the provider can properly assess what benefits are available for various medical procedures. Absent appropriate AOB language, a provider's billing administrators may find themselves stymied when attempting to obtain the health benefits that both the provider and patient deserve. A review of AOB form language may be warranted to ensure that a health care provider has the best possible chance of recovering benefits from ERISA plans successfully.

**Doug Dehler** is a shareholder and a member of the firm's Litigation group. Doug's practice includes advising clients on insurance coverage and health benefit issues.