Wisconsin Legislative Council
STUDY COMMITTEE MEMO

TO: MEMBERS OF THE STUDY COMMITTEE ON THE REGULATION OF ARTIFICIAL INTELLIGENCE IN WISCONSIN

FROM: Patrick Ward, Staff Attorney

RE: Disclosure of the Use of Artificial Intelligence (AI) in Communications and Requirement to Obtain Informed Consent for Health Care Services

DATE: October 8, 2024

At its meetings on August 29 and September 11, 2024, the study committee continued its discussion of various topics related to AI, including legislation from other states regarding the use of AI in health care. The study committee requested information about disclosure requirements in health care, including the role of informed consent.

DISCLOSURE OF AI IN HEALTH CARE

Wisconsin law does not specifically require the disclosure of the use of AI in health care. Informed consent, in the treatment context, may require the disclosure of the use of AI, but, as discussed below, informed consent in this context generally grants a health care provider discretion to determine what information must be disclosed.[1] Sample state laws from California and Utah are also discussed below, and are examples of a state requiring disclosure of the use of generative AI in certain interactions, including health care.

Informed Consent

Informed consent requirements in health care exist for both health care providers and hospitals.

Health Care Providers

Generally, a health care provider must obtain informed consent before treating a patient. As part of obtaining informed consent, the provider must inform the patient about the availability of reasonable, alternative treatments and about the benefits and risks of those treatments. The standard generally used to determine whether a patient is properly informed is the reasonable provider standard.[2] Under this standard, a provider must disclose any information that a reasonable provider would know and disclose under the circumstances. For example, physicians use a reasonable physician standard and

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[1] Informed consent requirements also exist in other health care contexts, including during the initial consultation by certain providers and before the release of certain records. [e.g., ss. 440.985 and 146.82 (1), Stats.]

[2] Wisconsin law includes more specific informed consent requirements for certain treatments, including providing an abortion and providing a sterilization procedure to a Medicaid patient. [s. 253.10, Stats.; DHS 107.06 (3) (d), Wis. Admin. Code.]

chiropractors use a reasonable chiropractor standard. For physicians and physician assistants, the standard considers a reasonable physician or physician assistant in the same or similar medical specialty.

The statutes exempt from the disclosure requirement certain information, such as certain risks and remote possibilities, and certain situations, such as an emergency. Relevant to the committee's work is the exemption from the disclosure requirement of "detailed information that in all probability a patient would not understand." [e.g., s. 448.30 (2), Stats.]

Hospitals

Wisconsin has adopted the federal Centers for Medicare and Medicaid Services' (CMS) Medicare Hospital Conditions for Participation as a uniform system of rules and standards for hospitals since 2016. This standard applies to all hospitals and provides a minimum standard, which may be supplemented by additional rules and standards promulgated by the Department of Health Services. [s. 50.36 (1), Stats.]

Under the federal standard, specific consent must be given and properly executed before performing a surgical procedure, except in an emergency. [45 C.F.R. s. 482.51 (b) (2).] The CMS interpretive guidelines for the rule specify that informed consent typically includes information relating to "potential short- and longer-term risks and benefits to the patient of the proposed intervention, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment."

Disclosure of Generative AI

As mentioned above, Wisconsin law does not require the disclosure of generative AI in health care interactions. As discussed below, California and Utah have laws that generally require such a disclosure.

California

A recent California law requires the disclosure of the use of generative AI in certain health care patient communications, unless the communication is read and reviewed by a human licensed or certified health care provider.[3] A health facility, clinic, physician's office, or office of a group practice must provide a disclaimer when it uses generative AI to generate written or verbal patient communication pertaining to patient clinical information. The law defines generative AI as AI "that can generate derived synthetic content, including images, videos, audio, text, and other digital content."[4]

The law specifies how the disclaimer must be displayed or communicated depending on the method of communication. For written communications that are not continuous online interactions, the disclaimer must appear prominently at the beginning of each communication. For written communications that are continuous online interactions, such as chat-based interactions, and video communications, the disclaimer must be prominently displayed throughout the interaction. For audio, the disclaimer is required verbally at the start and end of the interaction.

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[3] 2024 California Assembly Bill 3030.

[4] The law defines AI as "an engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments."

The patient communication must also include clear instructions that describe how a patient may contact a human health care provider; employee of the health care facility, clinic, physician's office, or office of a group provider; or other appropriate person.

Utah

As a part of a broader law related to AI, Utah requires the disclosure of the use of generative AI in two types of interactions.[5] First, in any interaction subject to regulation by Utah's Division of Consumer Protection, an entity regulated by this division must disclose whether a consumer is interacting with generative AI upon the request of the consumer.[6] The disclosure, if requested, must clearly and conspicuously inform the consumer that the interaction is with generative AI and not a human.

Second, a regulated occupation service provider that uses generative AI when providing services must prominently disclose the use of AI to the person receiving the services.[7] The disclosure must be provided verbally at the start of an oral exchange or conversation and through electronic messaging before a written exchange.

The law defines generative AI as an AI system that "(i) is trained on data; (ii) interacts with a person using text, audio, or visual communication; and (iii) generates non-scripted outputs similar to outputs created by a human, with limited or no human oversight."

The law provides that each violation of the disclosure requirements is subject to an administrative fine of up to $2,500 and that Utah's Division of Consumer Protection may bring an action in court to enforce the requirements. In such action, a court may declare a violation, issue an injunction, order disgorgement of any money received relating to the violation, order payment of disgorged money to a person injured by a violation, impose a fine of up to $2,500 for each violation, or other reasonable and necessary relief. The court must award reasonable attorney fees, court costs, and investigative fees to the consumer protection division if the Division of Consumer Protection is granted judgment or injunctive relief.

Options for Further Consideration

Several options for further consideration relating to disclosure of the use of AI, including generative AI, in health care are summarized below. This list of options is provided as a starting point for committee discussion and is not intended to be exhaustive.

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[5] Utah's law also defines AI-related terms, establishes liability for consumer protection laws involving AI, provides a process for the temporary mitigation of regulatory impacts during certain AI pilot testing, and creates an AI learning laboratory to assess technologies, risks, and policy. [Utah S.B. 149.]

[6] Utah's Division of Consumer Protection regulates consumer interactions through its general consumer protection law, as well as other more specific consumer protection laws, such as those in the areas of ticket website sales, motor vehicle warranties, and residential solar energy, among others.

[7] A regulated occupation is an occupation regulated by Utah's Department of Commerce that requires a person to obtain a license or state certification to practice the occupation. The types of regulated occupations include health care, trades, and business professionals, among others. The list of occupations can be found here.

Options for Disclosure of Generative AI

- **Take no action**. The study committee may determine that no action should be taken because the use of generative AI in health care interactions is an emerging use and industry standards are still being developed.[8]

- **California-style disclosure requirement**. The study committee may develop legislation that would adopt a disclosure requirement like California's, described above, which requires a generative AI disclaimer and instructions on how to contact a human when certain health care communications are made without appropriate human review.
    - o As an alternative, the disclosure could be required no matter the level of human review.

- **Utah-style disclosure requirement**. The study committee may develop legislation that would adopt a disclosure requirement for interactions involving regulated health care occupations, which would be similar to, but narrower than, Utah's disclosure requirement for interactions involving services provided by occupations that are regulated by Utah's Department of Commerce.[9]

Other Options

- **Sunset provision**. As a part of any draft legislation, the study committee could include a sunset provision that would repeal the law after a certain number of years.

- **Expand the generative AI disclosure requirement beyond health care**. The study committee may develop legislation that would adopt a disclosure requirement for interactions involving regulated occupations beyond health care occupations.
    - o As an alternative, the committee could develop legislation that adopts the disclosure requirement for consumer interactions like the requirement in Utah's law.
    - o As another alternative, the committee could develop legislation that adopts a disclosure requirement for interactions with state and local governments.

- **Consider changes to informed consent statutes**. The study committee may develop legislation that would amend the informed consent statutes.
    - o As an alternative, the committee may determine that no action should be taken because the general requirement for informed consent incorporates communicating the use of AI in patient treatment when deemed relevant and not otherwise exempt.

- **Nonlegislative recommendations or findings**. The study committee may determine that no legislation is required (or that it is unable to agree on legislation). Rather than recommending legislation, the study committee could memorialize certain recommendations or findings relating to disclosure requirements of the use of AI in health care. These recommendations or findings would then be included in the final report of the study committee to the Joint Legislative Council, or other correspondence, at the direction of the study committee.

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[8] For example, a recent article discusses how health care entities in the United States are using generative AI in patient interactions, and the article includes discussion of different perspectives on whether to disclose the use of generative AI to patients.

[9] The Wisconsin equivalent to Utah's Department of Commerce, with respect to regulated occupations, is the Department of Safety and Professional Services (DSPS). A list of professions regulated by DSPS can be found here; the list includes a profession's type (e.g., business, health, or trades).