

## **Informed Consent and the Covid-19 Pandemic**

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*This publication is intended to serve as a preliminary research tool for attorneys. It is not intended to be used as the sole basis for making critical business or legal decisions. This document does not constitute, and should not be relied upon, as legal advice.*

## **1. Introduction**

Application of the Doctrine of Informed Consent has become more complicated than usual during the novel coronavirus pandemic of 2020, providing more questions than answers about how to best serve patients, medical personnel, and potentially limit liability exposure. This publication seeks to provide some insight, suggestions, and resources as healthcare practitioners and organizations move through the ever-changing landscape of treating patients, operating businesses, and protecting healthcare workers while knowledge about the virus and attendant COVID-19 disease evolves, and public health directives regarding them change. Where the term physician is used, the terms dentist, psychologist, or other relevant practitioners may be substituted as appropriate.

For those readers who may not deal commonly with questions regarding informed consent, the following is a quick reminder of the basics of informed consent under “normal” conditions. This remains the baseline and touchstone for determining actions as we progress through the pandemic response. Discussions below about specific issues arising during the pandemic response will refer back to these basic principles.

## **2. The Basics**

“Informed consent” is a documented and ongoing process, not a form.<sup>2</sup> Informed consent forms are merely a piece of evidence (and rarely a strong one) that a patient provided *informed* consent to treatment. It is a discussion, or series of discussions between physicians (and in certain other circumstances, other licensed providers) and patients about various important aspects of a proposed course of treatment to help the patient make an informed decision about whether or not to undertake a proposed treatment.<sup>3</sup>

The Doctrine of Informed Consent is directly related to the common law concept of battery and the human and constitutional rights of self-determination, bodily integrity and control, and privacy.<sup>4</sup> As the court stated in *Union Pacific Railway Co v Botsford* (1891), “[N]o right is more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person.”<sup>5</sup> The law protects a person’s right to be safe in their person and possessions (trespass), and this includes being free from unwanted and unauthorized personal contact.<sup>6</sup>

Justice Cardozo set the standard regarding self-determination and a patient’s right to bodily integrity and control in the 1914 New York Court of Appeals case of *Schloendorff v Society of New York Hospital*:<sup>7</sup>

Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault [sic] for which he is liable in damages.<sup>8</sup>

In 1957, *Salgo v Leland Stanford Jr University Board of Trustees* addressed the issue of medical consent and added the all-important term “informed” to the medical consent requirement.<sup>9</sup>

The patient's right to remain informed about their medical care and situation is secured by Michigan statute (MCL 333.20201(2)(e),(f),(h),(j),(k),(n),(o)), federal and state regulations, and Michigan case law.<sup>10</sup>

The Doctrine of Informed Consent requires that the practitioner provide appropriate and sufficient information to the patient to allow the patient to make an informed decision about treatment.<sup>11</sup> The physician is legally responsible for the informed consent discussion, although minor portions of the process such as completing paperwork may be delegated to others, and additional practitioners may be required to have brief informed consent conversations with patients prior to administering treatments (e.g. respiratory therapy, physical therapy, occupational therapy) that should be documented as part of the ongoing informed consent process.<sup>12</sup> The physician and other licensed practitioners have a fiduciary duty to act in the patient's best interest at all times,<sup>13</sup> and the reporting structure for healthcare workers provides that physicians may be responsible for breaches of the fiduciary duties of those working at their direction, including with regard to the informed consent process.<sup>14</sup> Medical informed consent is ethically and legally mandated by the fiduciary responsibilities flowing from the patient-physician relationship.

In a negligence case alleging that the provider failed to obtain an informed consent, the question is whether or not the patient received the amount and type of information required to make an informed decision about undergoing treatment.<sup>15</sup> In an assault and battery intentional tort case, the question is whether or not the patient gave consent at all.<sup>16</sup> Assault and battery cases often center on whether consent was obtained, if the treatment or procedure differed substantially from the one that was authorized by the patient, or if the treatment or procedure exceeded the scope of the authorization.<sup>17</sup>

Informed consent includes four components: voluntariness, disclosure, comprehension, and competence/capacity.<sup>18</sup> Informed consent to treatment must be given voluntarily and be free of discernable coercion or duress.<sup>19</sup> Patients must receive disclosure of sufficient and relevant information regarding the proposed treatment such that an informed decision can be made.<sup>20</sup> The patient must be able to comprehend the information, meaning it must not be so jargon-laden that a reasonable patient could not understand it, and it must be in a language they can understand.<sup>21</sup> And finally, although

all patients are generally presumed to be medically competent to make decisions for themselves, they may at times lack the capacity for rational decision-making due to loss of consciousness, panic, pain, medication, or other confounding factors that the patient's physician may determine.<sup>22</sup> The basis for the loss of capacity arises out of the failure to meet the informed consent component of comprehension, and in order for the capacity to be absent, it must be determined medically and/or legally.

### **A. Implied Consent**

Routine procedures (like taking a patient's temperature) usually require only implied consent, for instance, the patient opens their mouth for the practitioner to put the thermometer in.<sup>23</sup> The patient has presumably presented themselves voluntarily for the routine procedure. This is also referred to as simple consent. But, for anything involving some level of risk, the patient or their surrogate must explicitly permit the practitioner to proceed.<sup>24</sup> Consent for treatment can be manifested either verbally, in writing, or it can be implied by accepting treatment in certain situations.<sup>25</sup> To override implied consent, a patient must offer an informed refusal. In *Cruzan v Director, Missouri Dep't of Health* (1990), the Court stated: "The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."<sup>26</sup>

### **B. Emergency Care Consent**

The emergency care exception concept predates the Doctrine of Informed Consent.<sup>27</sup> Obtaining sufficient and complete informed consent from persons presenting (voluntarily or not) for emergency care may also be covered under the concept of implied consent for healthcare treatment, depending on the exigency of the circumstances.<sup>28</sup> The rationale behind the emergency exception is that a patient should not be denied medical treatment when not in a condition to properly evaluate the data.<sup>29</sup> When the potential harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment, obtaining the patient's informed consent is not required.<sup>30</sup> When patients require emergency care, the time necessary for a complete discussion of the relevant factors regarding the proposed treatment may not be available, even if the patient has the capacity to understand, ask questions, and make an informed decision. The nature of an "emergency" necessitates implied consent, unless and until the patient can be deemed to have appropriate decision-making capacity and can competently make an informed decision about continuing or refusing further treatment following an appropriate discussion of the relevant factors with the physician.<sup>31</sup>

When a conscious emergency patient who appears to have appropriate decision-making capacity does not refuse treatment, the practitioner may have implied consent to proceed based on the patient's actions or inactions, depending on whether or not there was time enough or not to have an informed consent discussion. Unconscious patients presenting for emergency treatment are considered to have provided customary

precursor form of implied consent called “tacit consent” because consent is not implied from the patient’s conduct.<sup>32</sup> Implied consent arises out of tacit consent, and historically the common law has permitted medical personnel to provide care to critically ill persons or those with emergency conditions without fear of liability for failing to first obtain informed consent.<sup>33</sup> The United States Supreme Court even discussed “tacit consent” in an epidemic context in *Jacobson v Massachusetts* (1905).<sup>34</sup> This public policy principle is used every day in emergency medical care, but it is stated very clearly in states’ “Good Samaritan” statutes.<sup>35</sup>

### **C. Informed Consent Discussion Requirements**

A patient’s sufficient and complete informed consent is predicated on the physician providing the requisite and relevant information that will permit the patient to make an informed decision and grant permission to proceed with treatment. Patients expect physicians to provide medical advice and treatment using all of their knowledge and skill. Physicians are expected to act and disclose material and required information as other reasonably prudent physicians of their education, knowledge level, and experience would in the same or similar circumstances.<sup>36</sup> Michigan follows a variation of this standard discussed in Section F, below. In the seminal case of *Canterbury v Spence* (1972), the DC Circuit set forth the minimum physician disclosure requirements for an informed consent discussion with a patient, and set the first “reasonable man” standard.<sup>37</sup> Surgeons were directed to disclose “material” risks of surgery to the patient. The case defined material facts as the information patients need to make a medical decision.<sup>38</sup> Generally, the physician must provide the patient, or surrogate as appropriate, with the following information:

- the name, nature, and purpose, and expected outcome of the treatment
- all relevant risks and benefits and known or recognized major side effects
- reasonably available alternatives, and risks and benefits of such alternatives
- the consequences of not treating
- who will be providing the treatment, and where

Michigan adopted the following requirements in MCL 333.20201. Additional or situation specific requirements were adopted in other statutes as well.<sup>39</sup>

. . .

2(e). A patient or resident is entitled to receive adequate and appropriate care, and to receive, from the appropriate individual within the health facility or agency, information about his or her medical condition, proposed course of treatment, and prospects for recovery, in terms that the patient or resident can understand . . .

(f). A patient or resident is entitled to refuse treatment to the extent provided by law and to be informed of the consequences of that refusal. . . .

(h). A patient or resident is entitled to information concerning an experimental procedure proposed as a part of his or her care and has the right to refuse to participate in the experimental procedure without jeopardizing his or her continuing care.

(j). A patient or resident is entitled to know who is responsible for and who is providing his or her direct care, to receive information concerning his or her continuing health needs and alternatives for meeting those needs, and to be involved in his or her discharge planning, if appropriate.

. . .

Many courts are moving to a “reasonable patient” standard under which the sufficiency of disclosure is judged primarily on what information a patient would reasonably expect to receive from a physician in order to make an informed decision about the proposed course of treatment.<sup>40</sup> This requires the physician to tailor the information to the proposed treatment and disclose the information that an average, reasonable person would want to know before consenting to treatment.<sup>41</sup> This is often known as the “material risk” standard as defined in *Canterbury v Spence* (1972): “A risk is material when a reasonable person, in what the doctors knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy.”<sup>42</sup>

The American Medical Association and many other such organizations are endorsing the use of the Shared Decision-Making model (SDM) regarding the information that should be discussed with a patient about their medical condition and proposed treatment.<sup>43</sup> Although definitions vary wildly, SDM is defined by the Office of the National Coordinator for Health Information Technology (ONC) as “a process in which clinicians and patients work together to make decisions and select tests, treatments and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values.”<sup>44</sup>

Physicians and healthcare administrators should be clear that SDM (in any of its varied definitions) is *not* a legal standard for informed consent. It is a model for use by physicians in healthcare practice. For physicians, it should have as its base, the jurisdictional requirements of informed consent, and then should build on them to achieve the ends of SDM. According to the AMA Journal of Ethics:

SDM as best practice actually validates, augments, and enriches the process of informed consent by emphasizing patients' understanding and prioritizing of different medical interventions in light of their own values and lived experiences. Beyond improving informed consent, SDM can contribute to relationship building between health professionals and their patients through patient participation, engagement, and empowerment as well as through clinician presence, patient-specific focus, and improved communication. In addition to meeting ethical requirements, such constructive interactions of patients with their health professionals could actually improve outcomes and increase patients' understanding, trust, and adherence to treatment plans.<sup>45</sup>

Finally, more often courts are including the potential financial costs (to the patient) of treatment, information about themselves, such as physicians' experience, physicians' substance abuse and health conditions that might affect treatment, and physicians' financial conflicts of interest in the list of such information a patient would want to know.<sup>46</sup> Many of these cases reason that such information could be required under a physician-centered standard as well if other reasonably prudent physicians reveal such information.<sup>47</sup> This reasoning could also extend to a number of disclosure issues related to the COVID-19 pandemic. For either standard, the contents of the discussion and the signed consent form should be entered into the medical record.<sup>48</sup>

#### **D. Therapeutic Privilege and Informed Consent**

In circumstances in which the patient can and will make an informed consent decision, but the patient may suffer significant medical, mental, or emotional harm by some of the information conveyed in the informed consent process, the practitioner may withhold information that he or she deems potentially harmful to the patient.<sup>49</sup> This is referred to as therapeutic privilege.<sup>50</sup> The patient must be informed of the information as soon as the physician deems it safe to do so, and the practitioner must still disclose all information that would not be detrimental to the patient's health or well-being.<sup>51</sup>

Appropriate withholding of information only occurs in situations in which the risk of disclosure poses such a detrimental threat to the patient as to become injurious or contraindicated from a medical point of view.<sup>52</sup> Each patient's situation must be evaluated individually to determine what information might meet that definition.

#### **E. Surrogate Informed Consent**

In the event that the patient does not have the requisite decision-making capacity as determined by a physician (*medical* incompetency), or is *legally* incompetent (due to minority or a judicial determination), a surrogate decision-maker will stand in the place of the patient.<sup>53</sup> Surrogate decision-makers (also referred to as advocates or agents) may



provide informed consent to treatment of a patient following the sufficient and relevant disclosure of information to the surrogate decision-maker just as it would be given to the patient.<sup>54</sup> For Michigan residents, if the surrogate decision-maker was appointed by the patient in a properly executed Durable Power of Attorney for Healthcare (DPOAHC) (may also be referred to as an advance healthcare directive or patient advocate designation), or in a properly executed equivalent for residents of other jurisdictions (hereinafter collectively “advance directive”), and the surrogate has signified in writing their acceptance of the surrogacy, then the physician may generally rely on that advance directive as presumptive evidence of surrogacy.<sup>55</sup> If the patient did not properly complete an advance directive, the physician’s or organization’s legal counsel should determine the appropriate decision-maker. If the patient does not have a designated surrogate, then the healthcare organization may also have a policy and procedure for determining surrogacy.

Seeking and obtaining surrogate informed consent in the current COVID-19 environment can be extremely difficult. These situations involve numerous factors which will hopefully continue to be resolved as the remainder of the pandemic plays out, and in any case, before possible additional surges are experienced.

It can be difficult, if not almost impossible, for a healthcare provider to identify and contact a surrogate for the patient. Some patients arrive by ambulance or other means and are in an unconscious state. If there is no reasonable method of determining who the patient may have designated as a surrogate, or who may be eligible to serve as a surrogate in that instance, then the emergency care exception applies. A healthcare provider may presume that the patient would want to be treated, and that the treatment offered would be in the patient’s best interest.<sup>56</sup> The provider should make all reasonable efforts to determine the identity of a surrogate decision-maker, and these efforts along with the attendant circumstances at the facility should be noted in detail in the patient’s medical record.

If a legally eligible surrogate is identified at a later time, then the surrogate’s name and contact information should be noted in the patient’s medical record, and any additional informed consent discussions should be undertaken with the surrogate as long as the patient is medically unable to consent. All informed consent discussion requirements must still be communicated to the surrogate.

If a patient arrives conscious and able to consent, but does not speak English or cannot otherwise communicate effectively, then the nature of the circumstances at the facility also come into play. During a surge situation in an emergency department (ED) there may not be enough time or resources to provide an appropriate translator. (See Multilingual Information Tools in section 5 below). This may be an instance in which it might be permissible for an adult-friend or family member to translate. In situations such

as the coronavirus pandemic when all non-patient individuals are immediately told to leave the facility, and visitors are not permitted, providers may need to rely on the emergency care exception to the Informed Consent Doctrine if they cannot access translation services, or cannot identify and access a surrogate decision-maker who speaks English (or another language spoken by the physician or other provider) when translation services are readily available.

If an adult friend or family member is available to translate proposed treatment information to the patient in order to seek consent, the provider should take care to avoid medical jargon and make the required information as easy to understand and translate as possible. Because a patient in such a situation cannot speak English, it is presumed the patient cannot read an informed consent form written in English if a consent form is not readily available in a language they are able to read and comprehend. Providers may rely on verbal consent in such situations. (See Verbal Only Consent in section 4 below). It would be prudent for providers to also note the identity and contact information of the patient's designated surrogate (and a back-up surrogate) in the event one is needed in the future, something that can happen all too quickly with any patient, but especially in a highly contagious pandemic environment.

If a patient who does not speak English or cannot otherwise communicate effectively arrives in a non-surge, non-emergency circumstance, then the healthcare provider should locate a proper medical translator. The translator should translate the informed consent form so the provider can obtain the patient's written consent. In this situation, providers should not rely on verbal-only consent.

During the COVID-19 pandemic, numerous patients have arrived at healthcare facilities unconscious and without a proper advance directive, or a surrogate previously identified in the medical record. Many of these patients remain unconscious and unable to consent at a later time. Both COVID-19 patients and other patients suffering from serious medical conditions may experience multiple instances in which they lose their capacity to consent and then regain it at a later time. For example, many patients may go on and off a ventilator, or lose and regain consciousness multiple times over the course of their in-patient care. In these instances, the ability to provide informed consent to treatment transfers between the patient (when they can comprehend the informed consent discussion) and the surrogate. During a pandemic such as this, a significant number of confounding factors arise that make obtaining fully compliant informed consent from the surrogate extremely difficult for providers.

Whether or not a patient has designated a surrogate in an advance directive, or the surrogate is an eligible individual such as a spouse, parent, or adult child, visitation rules may prohibit the surrogate from being at the facility to have a face-to-face informed consent discussion with the physician or other provider. With the meteoric rise of

telemedicine resulting from the COVID-19 crisis, these discussions can be held over smart phones or tablets on teleconferencing software in order to obtain verbal consent. Informed consent conversations can also be held over the telephone, and verbal consent received from the surrogate. In such instances, it would be best if the provider obtained some form of written consent from the surrogate, even a text, email, or via recorded telehealth application, that could be placed in the medical record. If no other options are available, however, documenting fully and relying on verbal consent may be appropriate. (See Verbal Only Consent in section 4 below).

Problems arise if a facility develops an emergency pandemic policy that providers are not to engage with surrogates, or even family members over the telephone or use video applications for telemedicine purposes. In effect, such a policy results in either dispensing with the surrogate informed consent requirements altogether, or its enactment effectively relies solely on the emergency care exception (which likely only applies in some circumstances requiring informed consent), and the governmental immunity grants regarding care during the pandemic. (See Immunity from Liability in section 11 below). This is not a recommended course of action when the reasonable and simple employment of readily available technology can provide a means of informed consent compliance. (See the Reasonableness Standard in section F below).

Providers may encounter additional hurdles in situations when the patient does not have a properly executed advance directive. In the instance where an eligible surrogate has been identified, but the surrogate cannot enter the facility because of visitation restrictions, or for any other reason, contact information should be obtained if at all possible, and the surrogate contacted by telephone or videoconferencing if needed. If at any time during the course of treatment the patient is able to comprehend an informed consent discussion and provide informed consent to treatment, then that must be undertaken. Providers should always ask for and document the verbal instructions of the patient. If a patient is able to comprehend and sign a consent form, then that should be done and entered into the patient's medical record. If a patient is able to comprehend information, and the provider has diagnosed the patient as possibly facing a reduced life expectancy, the provider must inform the patient of the option of designating a surrogate decision-maker.<sup>57</sup> The provider should also take the opportunity to have the patient designate a surrogate decision-maker, and preferably a successor surrogate decision-maker,<sup>58</sup> if possible. A provider or facility cannot, however, require completion of such a document as a condition of treatment.<sup>59</sup> Explaining and having consenting patients sign an advance directive (preferably a DPOAHC for any patient from any jurisdiction) could give healthcare providers more direction if the patient later becomes incapable of consent.

Michigan recognizes the following types of advanced directives: a DPOAHC,<sup>60</sup> and a Do Not Resuscitate Order (DNR).<sup>61</sup> A patient advocate designation,<sup>62</sup> and an anatomical gift<sup>63</sup> are subsets of a DPOAHC, but can be executed as separate

documents.<sup>64</sup> Michigan does not formally recognize living wills,<sup>65</sup> but almost all providers and healthcare facilities will take living wills and other formal written evidence of a patient's medical care wishes into account, including properly executed advance directives from other jurisdictions if they would be valid in the state in which they were executed. Michigan does not have a reciprocity statute to honor advance directives executed in other jurisdictions.<sup>66</sup> A facility's legal counsel will determine what documents may be legally acceptable. Patients may execute a simple patient advocate designation authorizing an advocate (surrogate) to make healthcare decisions with or without other information or instruction.<sup>67</sup> To be valid it must be executed in the same manner as a DPOAHC, and must contain the same statutory language prescribed for the surrogate's (advocate's) acceptance.<sup>68</sup>

A DPOAHC is preferred because it necessarily contains the patient advocate designation, which also contains detailed information about the patient's healthcare wishes much like a living will, that may contain the anatomical gift designation if the patient chooses, and can provide the designated surrogate (advocate) with the power to make legal, financial, and medical *healthcare-related* decisions.<sup>69</sup> A DNR Order must be executed on a designated and separate form, but like a separate living will, it can be incorporated by reference into a DPOAHC.<sup>70</sup> This form can be downloaded from Michigan.gov.<sup>71</sup> A properly and fully completed DPOAHC should provide the surrogate and healthcare providers with the identity of and authority granted to the surrogate, and sufficient and necessary information about a patient's medical care wishes.<sup>72</sup>

For the DPOAHC to be valid the patient must be at least 18 years old, competent and able to express their wishes voluntarily and not under any duress, fraud or undue influence,<sup>73</sup> must sign or be able to direct a notary to sign for them if necessary,<sup>74</sup> must have two adult witnesses who are not family members or the patient advocate (as well as other limitations on witnesses) sign,<sup>75</sup> the document must be dated,<sup>76</sup> the surrogate and successor surrogate must also accept surrogacy by their signatures,<sup>77</sup> and it must be in the patient's medical record with the facility or physician before it is implemented.<sup>78</sup> Most healthcare facilities have DPOAHC form documents readily available, and they can be easily downloaded from many major hospital systems and state advocacy groups.

Facilities that do any of the following may create an unreasonable legal situation and could potentially fail to obtain appropriate surrogate informed consent on behalf of a patient:

- Fail to allow patients admitted during the COVID-19 pandemic to complete and sign a new DPOAHC or simple patient advocate designation form.
- Fail to accept receipt of a DPOAHC drafted by the patient's lawyer and assist the patient with signing the document in situations where visitors are unable to access the facility.

- Fail to permit a facility's or provider's volunteers, or non-employee pastoral care representatives to serve as witnesses to the signing of DPOAHCs or patient advocate designations, or otherwise fail to permit or assist patients' participation in remote videoconferences to facilitate remote witnessing or notarization.<sup>79</sup>

Discussion of guardianships is beyond the scope of this article, but guardianship status may also be factor in a surrogate decision-maker situation.

Facilities must ensure that their policies and actions do not actively or deliberately seek to avoid informed consent requirements or curtail patient rights when the patient is unable to personally provide informed consent. It would violate a number of laws,<sup>80</sup> regulations,<sup>81</sup> accreditation requirements,<sup>82</sup> organizational practice bylaws, policies, and standards,<sup>83</sup> and ethical standards.<sup>84</sup>

A physician caught in a situation as described above would unfortunately experience little organizational support for the execution of the physician's legal and ethical requirements to obtain informed consent, and even less support for the welfare and rights of the patient. In such circumstances physicians should go back to the basics of informed consent: act as reasonably as the situation will allow, act in the patient's best interest at all times, use best efforts to comply with the informed consent requirements and the intent of the doctrine, get an informed consent document signed if possible, and document everything to the best of the physician's ability.

## **F. The Reasonableness Standard and Its Application to COVID-19 Situations**

As a general rule, informed consent issues fall under the umbrella of professional liability (professional malpractice), and therefore under torts. As a tort, the reasonable person, organization, or practitioner standard generally applies. This is often referred to as the "prudent" standard as well. Although general English dictionaries can provide completely different definitions for reasonable and prudent, Black's Law Dictionary defines "prudent" as the ability to govern and discipline oneself by the use of reason, and caution or circumspection as to danger or risk. It defines "reasonableness" as being in accordance with reason.<sup>85</sup>

Michigan follows the "ordinary learning, judgment, and skill" standard as stated below.

As stated in the Michigan Model Civil Jury Instructions:

"Professional negligence" and "malpractice" are the same. They mean the failure to do something that a [ name profession ] of ordinary learning, judgment and skill in [ this community or a similar one / [ name

particular specialty ] ] would do, under the same or similar circumstances as in this case. Professional negligence, or malpractice, can also mean doing something that a [ name profession / name particular specialty ] of ordinary learning, judgment and skill would not do, under the same or similar circumstances as in this case<sup>86</sup>

Michigan Attorney Norman D. Tucker of Somers Schwartz, PC, states:

The standard is not what someone else would have done, what ideally should have been done, but what the “ordinary” physician or nurse would have done; this is sometimes referred to as the “average” health care person of the same specialty. Some think the law is what the “reasonably prudent” physician or nurse would have done; that is not the law in Michigan and there is a difference.<sup>87</sup>

It should be noted that the standard is what the ordinary or average healthcare person of the same specialty in the particular or similar community would have done *under the same or similar circumstances*. It could be reasonably argued that this language could encompass extreme and novel situations such as the COVID-19 pandemic.

In any event, applying the physicians’ knowledge, judgment, and skill, acting as others of the physicians’ specialty would in the same or similar circumstances, and acting reasonably and with prudence under the circumstances rarely if ever, will entail departing from, or dispensing with the informed consent requirements altogether. As noted above, there are sound principles for emergency patient situations. As for other patients, the right to remain informed about their medical care and situation continues, and informed consent is still required in all situations in which it can be had, even if not by customary means and methods.

Common sense adaptations to provide informed consent disclosures, engage in informed consent discussions, and to obtain some written consent (such as a completed form) may require using various electronic and other means in circumstances such as quarantine procedures, lack of patient capacity, or the lack of immediate access to a surrogate because of visitation restrictions. In these instances, faxes, emails, and photographs can be used to obtain a copy of a signed consent form, and documentation in the patient’s medical record of the information discussed and verbal consent if given, along with the identities of witnesses to any stage in the informed consent process.

***See endnotes for a helpful resource on COVID-19 adaptations to the informed consent process.***<sup>88</sup>

### 3. Conveying Risks of Covid-19

Although not related to the COVID-19 pandemic, the following quote from Donald Rumsfeld (2002) seems to perfectly address the COVID-19 state of knowledge issue:

We know there are things we know we know. We also know there are known unknowns; that is to say that we know there are some things we do not know. But there are also unknown unknowns—the ones we don't know we don't know.<sup>89</sup>

One of the underlying presumptions of the informed consent process is that the physician knows the *relevant or material* risks associated with a proposed course of treatment and can, therefore, disclose and explain them to the patient or surrogate. With the novel coronavirus and COVID-19, there are so many unknowns, and in many instances, even assumptions or best guesses cannot be made as to risks, benefits, efficacy, or even suitability of certain treatments and procedures.

When the risks and benefits of a proposed treatment are unknown, the proposed treatment cannot be compared or weighed against the risks and benefits of alternative treatments. Certainly, with regard to treatment options for the sickest of COVID-19 patients, risks and benefits of pharmacotherapies being proposed under U.S. Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs)<sup>90</sup> cannot be accurately disclosed because the drugs have never been studied in the COVID-19 context. One cannot even state probable risks and benefits of the drug as compared to not treating with the drug at all. It is difficult to help a patient manage expectations and make informed decisions in such situations, and very difficult to document what is not known and therefore cannot be disclosed.

Relying on the “standard of care” to determine those risks and benefits is not possible in this situation either, because as of the date of this article, there are no nationally established standards of care to treat COVID-19. Even protocols that provide some guidance are changing within weeks, and it is unlikely that a protocol or course of treatment and care will quickly become a standard that providers may rely on to determine relevant or material risks.

Healthcare providers face particularly difficult informed consent issues relating to the disclosure and discussion of relevant and material risks during this pandemic. The following are just a few of these issues:

- Do individuals seeking non-coronavirus healthcare services have the right or need to know how possibly contracting the virus could affect the condition and treatment being discussed by the patient and physician?

- Is that a relevant or material piece of information that should be communicated by the physician, dentist, or other practitioner in all instances because this is a declared pandemic, or should it only be discussed with regard to medical conditions that have already been identified as increasing the risk for contracting the virus or for contributing to increased severity?
- Is the potential to contract the virus while in the hospital for medically necessary, time-sensitive procedures a relevant or material risk that must be disclosed and discussed?
- Is the shortage of personal protective equipment, ventilators, or medical equipment or supplies an issue that must be disclosed to patients as it may have an effect on their care and treatment?

These are questions even the most prominent bioethicists and legal scholars have yet to fully tackle. Analysis and recommendations vary significantly depending on the viewpoint of the analyst making them. Information about how the virus and COVID-19 impact different patients, different medical conditions, different treatments for COVID-19, long-term effects, and any other medical factors are changing almost daily as global researchers continue to uncover more information about this unique virus. Stable information and guidance on which to rely is difficult to come by at the moment, and possibly for the foreseeable future.

What providers can be certain of in wrestling with these issues is that persons with COVID-19, those who suspect they may have it, and those who have medical needs that have nothing to do with COVID-19 are all entitled to information about how relevant and material risks related to the existence and transmission of the novel coronavirus and COVID-19 may affect their medical condition or situation and their proposed course of treatment. As Michigan case law requires, physicians are expected to act with learning, judgment, and skill, but might do better to also act as other *reasonably prudent* physicians in the same specialty, with similar knowledge and experience would act in the same or similar circumstances.<sup>91</sup>

Because information is emerging at a significant clip in an environment of social distancing, and in many cases “surge” crises, physicians may not be able to keep up with all of the latest information in order to determine what is relevant or material to the informed consent discussion. The information one patient or surrogate receives one week may be outdated and contraindicated the next (related to the use of hydroxychloroquine, or the effect of the virus on children or young adults, for example). In such circumstances, physicians should rely on the most up-to-date information available to them at the moment, and continue to request that their facilities keep them updated as often as possible. It may be better to err on the side of caution and relevance or materiality regarding particular pieces of information, than not, even given the federal and state



grants of immunity as those have not yet been tested. Prudence may be the take-away here. Again, go back to the basics: apply learning, judgment, and skill, and act reasonably, prudently, in good faith, in the best interests of the patient at all times, and with the best intent to comply with the letter and spirit of the law. Just as informed consent is particular to each individual patient and condition in “normal” times, so is it individual to patients in a pandemic.

***See endnotes for a helpful resource on surgical consent and COVID-19.<sup>92</sup>***

#### **4. Use of Verbal Only Consent in ED or Other Rule-Out Areas**

Any Medicare or Medicaid participating provider is subject to the Centers for Medicare & Medicaid Services (CMS) Medicare Conditions of Participation (CoPs). There are several Medicare regulations that directly or indirectly address informed consent. Medicare Provider regulations state that to maintain Medicare enrollment a provider must certify that it meets, and continues to meet compliance with Title XVIII of the Act and applicable Medicare regulations (42 CFR 424.516(a)(1)). Medicare Hospital CoPs provide additional reference. Under 42 CFR 482.11 hospitals must be “in compliance with applicable Federal laws related to the health and safety of patients, and must assure that personnel are licensed or meet *other applicable standards that are required by State or local laws.*” (Emphasis added). This would very likely include state law informed consent requirements.

Pursuant to 42 CFR 482.13(a) and subsections, “A hospital must protect and promote each patient’s rights” (482.13). “A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible” (482.13(a)(1)). Similarly, 42 CFR 482.13(b) and subsections provide “the patient has the right to participate in the development and implementation of his or her plan of care” (482.13(b)(1)). And 42 CFR 482.13(b)(2) provides:

The patient or his or her representative (*as allowed under State law*) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Further guidance regarding informed consent and 42 CFR 482.13(b) is provided in the Medicare Interpretive Guidelines for that CFR in the CMS State Operations Manual.<sup>93</sup> The Interpretive Guideline states:

The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.

...

Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent.

Medicare CoP 42 CFR 482.24(c)(4)(v) requires that a patient's medical record include "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent."

On March 30, 2020, CMS temporarily waived compliance with and enforcement of 42 CFR 482.24(a) through (c), including (c)(4)(v) stated directly above, retroactive to March 1, 2020. That rule relaxation was again stated in the 7/30/2020 update from CMS.<sup>94</sup> The state law requirements, however, have not been waived.

The information to be disclosed to a patient is required by standards set in state law, and the ethical requirements for the same as set by different providers' professional associations (with some being more or less inclusive of various pieces of information). Medicare appears to leave the content of the informed consent disclosures to state law, with the requirement to perform it being tied to patient's rights, and the documentation of it set forth in a particular CFR as noted above.

Also as noted above, there are circumstances that permit verbal only consent for treatment. All circumstances that do not meet those criteria require complete, proper, and documented informed consent to the best of the physician and facility's ability given the unusual circumstances of the pandemic.

One of the big concerns in this pandemic response has been the potential for virus transmission from shared items, not only in the provision of healthcare services but also during patient administrative interactions as well. In the healthcare context that includes pens, paperwork, and devices. This situation definitely throws a wrench in the standard signature process for consent forms. Practitioners are asking if relying solely on verbal consent is sufficient. The answer is likely, no.

In emergency departments (EDs) and other Rule-Out (R/O) areas,<sup>95</sup> the basic doctrines of implied and emergency consent apply (as appropriate to the patient), so relying on verbal consent instead of express written consent as a form of proof of obtaining informed consent is not typically a factor. If the situation permits implied consent, then usually no verbal or express consent is needed at all (blood draw, nasal swab) because the patient's actions imply consent. In an emergency situation, implied or presumed consent kicks-in, so no verbal or written consent is required. In all other contexts, and for patients who are being seen in various types of healthcare entities for virus and non-virus related issues, providers must document the patient's consent to treatment.

The Dana Farber/Harvard Cancer Center provides some additional information:

An important method to avoid infection transmission is to avoid the sharing of pens (including electronic) and pencils among patients and staff. One of the most common scenarios for this practice is obtaining patient signatures on written informed consents and on numerous administrative forms during registration (e.g., non-emergent visits, emergency department, observations, ambulatory, etc.) and during patient care activities in all clinical settings (e.g., hospital, ambulatory, post-acute, home care). During this emergency response period, documented verbal consent in lieu of patient signature should be obtained as outlined below:

- Registration and other administrative activities – staff to fully inform the patient of what they are consenting to (or hand the patient paper, point to sign, etc.) and document consent was verbally received. This would apply to the general consent to treatment, financial consent and acknowledgment of Notice of Privacy Practices and other administrative forms.
- Clinical settings – the clinician completes the consent discussion, seeks verbal consent from the patient and signs the Informed Consent Form, at the patient's direction, where the patient would otherwise have signed the form. This process would also apply to discharge paperwork

and other forms completed and signed by the patient during the course of care.<sup>96</sup>

Go back to the basics: informed consent is a conversation and a process, not a form. Providers must document conversations and informed consent disclosures, patients' or surrogates' questions, witnesses, date and time, clinical judgment factors, and if possible a signature on a form that reflects all the required disclosures. Providers and facilities must be open to receiving that consent document in any form – fax, pdf, or even photograph or jpg. Even if a signed form cannot be obtained by any means, documenting all the particulars of the physician-patient conversation means the provider and facility are still not relying solely on verbal consent without a written record. Having witnesses and noting witnesses' names, important details, and patient questions in the record is often stronger evidence of consent than any consent form.

***See endnotes for a helpful resource on clinical research consent and COVID-19.<sup>97</sup>***

## **5. Use of Multilanguage Information Tools Given Publicized Studies Regarding Impact on Minority Populations**

The novel coronavirus and COVID-19 disproportionately affects populations likely to face health literacy and language barriers, especially with respect to informed consent discussions. It is therefore imperative that patients and surrogates receive information in terms they can comprehend, and in a language they can understand. Hospitals, health plans, clinics, nursing homes, physicians and other providers that receive Medicare, Medicaid or other sources of federal funds have an obligation to provide “qualified interpreters” and written translated documents for Limited English Proficiency (LEP), Deaf and hard of hearing (HOH).<sup>98</sup> In fact, failing to provide language access services to LEP patients is a form of national origin discrimination. Case law all the way up to and including the United States Supreme Court establishes this basic principle.<sup>99</sup>

Three federal laws (Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and the Affordable Care Act) require that providers who receive federal funds take reasonable steps to provide oral interpreters and written translated materials to LEP and Deaf and HOH patients. Newly adopted changes to Section 1557 (45 CFR part 92) of the ACA in 2016 brought about two key changes. First, providers must now use “qualified” medical interpreters when treating LEP and Deaf and HOH patients. Second, LEP patients, for the first time, were granted the right to sue providers for language access violations under Section 1557.<sup>100</sup>

Providers are not only prohibited from relying on minor children as interpreters, they are also instructed not to rely on minor children to “facilitate communication” with LEP patients. The only exception to this rule is “an emergency involving an imminent threat to the safety or welfare of an individual or the public where no qualified interpreter

is immediately available.”<sup>101</sup> Adult family members and friends may be used as medical interpreters in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter immediately available (which may be the case in times of surge during a pandemic).<sup>102</sup>

Adult family members and friends may be used as medical interpreters where the LEP person “specifically requests that the accompanying adult interpret or facilitate communication and the accompanying adult agrees to provide such assistance.” However, providers are not relieved of their legal duty to provide a qualified medical interpreter if more appropriate when an LEP patient elects to use an adult family member or friend as “reliance on that adult [family member or friend must be] appropriate under the circumstances.”<sup>103</sup>

The rule severely restricts bilingual or multilingual staff without formal training in medical interpreting from serving as medical interpreters. Only “qualified” bilingual or multilingual staff may serve as interpreters. The rule makes it illegal to require an individual with limited English proficiency to provide his or her own interpreter during medical encounters.<sup>104</sup>

The rule significantly expands the range of individuals to whom healthcare providers owe a legal duty to provide language access services. It imposes a general requirement on providers to “take reasonable steps to provide meaningful access to *each individual with limited English proficiency eligible to be served or likely to be encountered* in its health programs and activities.” When applying for federal financial assistance, providers must, as a condition of the application, submit assurances that its health programs and activities will be operated in compliance with Section 1557 of the ACA.<sup>105</sup>

The basic purposes of informed consent are to protect the patient’s right to make autonomous decisions, protect patients from battery, protect bodily integrity, prevent unwanted medical treatment, and support patient-defined goals.<sup>106</sup> Some would also add to share decision-making between the patient and physician, although not all courts agree. These purposes must be met for all patients, not just for patients with English proficiency, or with full hearing and vision. The ethical principles of autonomy, beneficence and justice apply to all patients equally.<sup>107</sup>

***See endnotes for helpful resources on interpreter requirements and COVID-19.***<sup>108</sup>

**6. Information about Exposure Risk, Best Efforts to Provide a Safe Environment, and the Use of Statements Regarding Compliance with Accreditation Organization or CDC Guidelines**

With pandemic-related informed consent issues arising daily, numerous organizations have drafted “acknowledgment” forms for patients to sign. These forms acknowledge the risks and unknowns related to the virus and COVID-19, and

acknowledge that the patient is aware that the healthcare organization and its providers are providing their best efforts to ensure the safety of patients, employees, and others. The question has become: “how broad should statements be about the potential risk of contracting the virus at the facility, and providing best efforts to ensure the safety of patients, employees, and others?” Should statements be made that the organization complies with all CDC, state, or accreditation organization (e.g., TJC, DNV, HFAP) requirements or guidelines?

Many organizations and professional associations have drafted sample acknowledgment forms, and forms combining the acknowledgment statements in an informed consent document. Links to samples are provided below. Each includes something the others do not. There is no consensus anywhere about what should be included, and the extent of the information to be included.

Second, when making statements about efforts to provide safe environments, testing, and other topics, it would be preferable to not use superlatives. Providing “best efforts” is preferable to “doing everything possible” to ensure patient safety and a safe environment. Using appropriate language sets expectations. If the document claims efforts are the “best in the industry” then that sets a standard and an expectation. Falling short of that expectation may open the door for litigation if a patient is infected at the facility.

Similarly, stating that the facility is complying with all CDC guidelines or accreditation requirements may be overkill or not enough effort in the pandemic environment, or create a moving target that simply cannot be hit on a constant basis (changing CDC guidelines). State only what can be substantiated.

Other healthcare counsel, professional liability insurers, and professional associations take a different view. For example, the California Dental Association (2020), advises its members:

An informed consent form, by itself, is insufficient to shield a medical provider from liability and creating one specific to COVID-19 may provide a dentist with a false sense of security. Rather, an informed consent form is designed to be a part of a process of obtaining a patient’s agreement, following an explanation and discussion of why treatment is needed, as well as the risks of and alternatives to a procedure. For emergency procedures contemplated during the current COVID-19 situation, the informed consent process for that procedure is sufficient.<sup>109</sup>

When caught between these types of competing viewpoints, go back to the basics:

- What is in the best interest of the client (to whom the attorney owes a fiduciary duty)?
- What is in the best of interest of the client's patients (to whom they owe a fiduciary duty)?
- Which perspective best meets the purposes and requirements of the doctrine of informed consent?

***See endnotes for helpful resources, including a consent form for an elective procedure during COVID-19.<sup>110</sup>***

## **7. Informed Consent and Research Participation**

Many major hospitals and systems are already researching potential drugs and other therapies to treat COVID-19. Such facilities likely already have revised their clinical research informed consent policies, procedures, and forms. Smaller facilities may also wish to use U.S. Food and Drug Administration "EUA" pharmaceuticals or other treatments under consideration and participate in research efforts, which may require changes to their informed consent protocols applicable to this type of research. New treatments, potential vaccines, and other forms of testing and diagnosis will surely be forthcoming, and will also require informed consent protocols.

Federal law requires that healthcare providers obtain appropriate informed consent from human subject research participants. Those requirements are referred to as the Revised Common Rule, and can be found at 45 CFR Section 46.

***See endnotes for helpful resources on informed consent and human subject research and COVID-19.<sup>111</sup>***

## **8. Telemedicine Informed Consent**

If it wasn't before, telemedicine is now surely here to stay. The pandemic and attendant closing of medical practices and other facilities have created the necessity to employ telemedicine on a massive scale for the continued provision of medical care to patients. According to the Center for Connected Health Policy:

Medicare does not require that an informed consent be obtained from a patient prior to a telehealth-delivered service taking place, but a majority of states either require informed consent be obtained within their Medicaid program or in their statute or rules regulating healthcare professionals. This may be due to concerns over health information security or ensuring whether the patient fully understands what is to take place.

In telehealth, informed consent is used to explain what telehealth is, lay out the expected benefits and possible risks associated with it to a

patient, and explain security measures. Typically, prior informed consent is reserved for invasive procedures and experimental studies, and not required when a patient is offered a choice in how they wish to receive services. Requiring a prior written or verbal informed consent for any telehealth consultation and treatment misrepresents telehealth as a different form of service, rather than as a useful tool that enhances diagnostic and treatment services.<sup>112</sup>

For the purposes of informed consent, physician-patient discussions over telemedicine should be viewed as if it were any other in-person healthcare encounter. Telemedicine informed consent forms existed prior to the pandemic, but now many have been revamped to address the particular aspects of the pandemic as they may impact patient care and treatment options. Patients must understand how informed consent works in a telehealth environment. Physicians need to ensure their standard informed consent documents are updated to comply with state laws and can be sufficiently individualized to address a patient's particular medical situation. Informed consent is never a "one-size-fits-all" endeavor.

***See endnotes for helpful resources, including an example telehealth informed consent form and COVID-19.***<sup>113</sup>

#### **9. Documentation of Informed Consent in a COVID-19 Surge/Non-Surge Situation**

General concepts for documenting informed consent during the initial stages of a pandemic are addressed above. During a non-surge period, documentation should be fully compliant with state and federal requirements. Refined processes, procedures, and updated informed consent forms should be implemented during the non-surge period to be ready for use in surge periods. It is likely that there may be additional surge periods to come.

Matthew Keris, an attorney with Marshall Dennehey Warner Coleman & Goggin, sets out some great advice on electronic medical record (EMR) documentation, in general, in this April 2020 article that applies to the documentation of informed consent as well.<sup>114</sup> The following are relevant excerpts.

- Be a good historian. Years from now, you will need to remind and educate counsel, judges, and juries of the magnitude of this world pandemic. You may need to compare COVID-19 period numbers to your typical census to demonstrate that the hospital was much busier than normal, which would impact documentation practices.



- Keep accurate hospital staffing records. It will be important to show an increased reliance of locum tenens, agency nurses, “unretired” health care providers and volunteers. Staffing information will be critical in explaining the EMR for care given in this time period.
- Document duties and privileges that have been expanded or temporarily changed. When examining the record at a later date, these new responsibilities may explain why information was documented by a certain person.
- Limit the “footprint” in the EMR after the patient is discharged from the hospital. One unsettled area of the law is whether a privilege can be attached to an audit trail. In states that hold that the audit trail is an “original source” document, similar to the hospital chart, attorney or peer review involvement within the EMR may not be protected.
- Advocate and defend your decisions and practices from the COVID-19 period. Judges and juries will remember and understand the hard decisions made during this unprecedented time period. They will be forgiving of occurrences and practices that broke from the norm. The rightful goodwill endeared upon health care providers will not quickly dissipate. Years from now, when others second-guess or scrutinize decisions made during this period, with the benefit of hindsight, return fire and fight back with facts.

***See endnotes for a helpful resource on documenting consent in the EMR.<sup>115</sup>***

## **10. Informed Consent Requirements and the False Claims Act**

Whether or not a pandemic or other public health emergency has been declared, providers must obtain informed consent to comply with claims submission requirements, especially for Medicare and Medicaid claims. As stated in Verbal Only Consent, section 4 above, CMS temporarily waived compliance with, and enforcement of the record-keeping requirements of 42 CFR 482.24(c)(4)(v) retroactive to March 1, 2020. Numerous other regulatory requirement waivers were implemented as well.<sup>116</sup> The many temporary waivers will affect the analysis below. Because claims submissions requirements are nuanced and complex, we encourage the reader to use the discussion below as a *starting point* to analyze how the failure to obtain informed consent (or departure from any other CMS requirements) may result in potential false claims and other compliance consequences.

Chapter 15 of the Medicare Integrity Manual defines enrollment as the process that Medicare uses to grant Medicare billing privileges.<sup>117</sup> To provide services and bill Medicare for the provision of such services, a provider must be enrolled in the Medicare program via the applicable CMS enrollment form.<sup>118</sup> To become an authorized institutional Medicare participating provider in both Medicare Part A and Part B, the provider certifies at the end of the application form that it agrees to be legally and financially bound

... [t]o the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, and I authorize the Medicare fee-for-service contractor to verify this information. *If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact* in accordance with the time frames established in 42 CFR 424.516(e). (Emphasis added).<sup>119</sup>

Application form CMS 855i, for physicians and non-physician practitioners, further extends the relevant certifications and acknowledgements:

You MUST SIGN AND DATE the certification statement below in order to be enrolled in the Medicare program. In doing so, *you are attesting to meeting and maintaining the Medicare requirements* stated below.

Under the penalty of perjury, I, the undersigned, certify to the following:

1. I have read the contents of this application, and the information contained herein is true, correct, and complete. *If I become aware that any information in this application is not true, correct or complete, I agree to notify my designated Medicare Administrative Contractor of this fact* in accordance with the time frames established in 42 CFR 424.516.

2. I authorize the Medicare Administrative Contractor to verify the information contained herein. I agree to notify the Medicare Administrative Contractor of any change in practice location, final adverse legal action, *or any other changes to the information in this form* in accordance with the timeframes established in 42 CFR 424.516. . . . .

3. I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that *any deliberate omission, misrepresentation, or falsification of any information* contained in this application *or contained in any communication supplying information to*

*Medicare, or any deliberate alteration of any text on this application, may be punishable by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.*

*4. I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 USC section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 USC section 1395nn (section 1877 of the Social Security Act)).*

...

*6. I agree that any existing or future overpayment made to me, or to my business as reported in section 4A, by the Medicare program, may be recouped by Medicare through the withholding of future payments.*

...

*8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.*

...

(Emphasis added).

Medicare regulations state that to maintain Medicare enrollment a provider must certify that it meets, and continues to meet compliance with Title XVIII of the Act and applicable Medicare regulations.<sup>120</sup>

The Medicare Medical Records Services Condition of Participation (CoP) regulation, 42 CFR 482.24(c)(4)(v), requires that a patient's medical record include "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent." CMS later interpreted this regulation<sup>121</sup> to mean "[a]n informed consent form, in

order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law *or regulation*.” (Emphasis added). See The Basics, and attendant subsections, in section 2 above for Michigan law informed consent requirements.

As previously stated, there are several Hospital Medicare regulations under the CoPs that indirectly address informed consent, other than in the documentation aspect noted above: 42 CFR 482.11, 482.13(a) and (b), and the CMS State Operations Manual Interpretive Guidelines for each.

Regarding informed consent and human subjects research (such as clinical trials for COVID-19 related treatments and vaccinations), federal regulations governing informed consent fall under 45 CFR 46 Subpart (A), and are referred to collectively as the Revised Common Rule.<sup>122</sup> The specific informed consent regulation for human subjects research, including the requirements and process for informed consent can be found at 45 CFR 46.116, and the documentation requirements can be found at 45 CFR 46.117.

Concerning this last rule, the pandemic has disproportionately affected the elderly and those with pre-existing conditions that render them fully disabled, and those with end-stage renal disease, which is the population that comprises Medicare beneficiaries. Because so many inpatient and outpatient clinical drug and vaccine trials are being commenced during this pandemic, it is reasonable to assume that any number of Medicare beneficiaries may be participating in these clinical trials. The CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials provides coverage for “the routine costs of qualifying clinical trials ... as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.” The specifics of this NCD may be found at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true>. Among the requirements, however, is the stated requirement that the clinical trial comply with Federal regulations relating to the protection of human subjects.

If any of the aforementioned informed consent requirements are skipped, completed improperly, or the documentation is not in compliance with Medicare documentation regulations (42 CFR 482.24(c)(4)(v)), then the claims submitted may be considered false claims under the False Claims Act.

The False Claims Act (FCA)<sup>123</sup> imposes significant penalties on anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” to the Federal Government,<sup>124</sup> “conspires to commit a violation of

subparagraph (A),(B),(D),(E),(F), or (G),”<sup>125</sup> or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”<sup>126</sup>

The FCA defines the terms “knowing” or “knowingly” as a person, with respect to information, who has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information.<sup>127</sup> It does not require proof of specific intent to defraud.<sup>128</sup> Further, the FCA defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment *or receipt* of money or property.” (Emphasis added).<sup>129</sup>

To state a claim under the FCA,<sup>130</sup> the relators (or federal government) must show: “(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.”<sup>131</sup> The falsity and materiality allegations must satisfy FRCP 9(b) and be plead with particularity. The scienter information, including malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.<sup>132</sup>

In 2016, the Supreme Court decided *Universal Health Services, Inc. v. United States ex rel. Escobar*.<sup>133</sup> The *Escobar* case addressed the issue of whether the submission of a claim to the government for payment for provided Medicaid or Medicare services impliedly certified that the claimant was in full compliance with all relevant and required statutory and regulatory requirements, and whether failing to disclose noncompliance with a statutory, *regulatory* or contractual requirement constituted a false claim under the FCA. This is more commonly known as “implied certification.” The respondents in *Escobar* (supported *amicus curiae* by the federal government) argued that a defendant who knowingly bills the government for services without disclosing a failure to satisfy material conditions for the delivery of those services, and knows its failure to disclose additional information renders its statements materially misleading, has submitted a false claim under the FCA.<sup>134</sup>

The Court in *Escobar* set forth a two-pronged test for implied certification under 31 USC 3729(a)(1)(A):

[T]he implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations half-truths.<sup>135</sup>

The Court held that FCA liability can attach for violating statutory or regulatory requirements, whether or not those requirements were designated in the statute *or* regulation as conditions of payment.<sup>136</sup> Specifically, the Court in *Escobar* held that FCA

[l]iability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, *regulatory* or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading." (Emphasis added).<sup>137</sup>

The Court also stated, "What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."<sup>138</sup> It followed up with, "A misrepresentation about compliance with a statutory, *regulatory*, or contractual requirement must be *material* to the Government's payment decision in order to be actionable under the FCA. The FCA's materiality requirement is demanding." (Emphasis added).<sup>139</sup>

Further, the Court provided several factors that would control the "materiality" analysis, but did not state if any single factor would, or could be dispositive:

- whether compliance with a statute is a condition of payment;
- whether the violation goes to "the essence of the bargain" or is "minor or insubstantial;"
- whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations; and
- whether the government would likely refuse payment had it known of the regulatory violations.<sup>140</sup>

To ensure that the FCA is applied in proper context, the Court also noted that the FCA is not "an all-purpose antifraud statute" or a "vehicle for punishing garden-variety breaches of contract or regulatory violations."<sup>141</sup>

In sum, the Court in *Escobar* held that the alleged violation of a statute, regulation, or contract giving rise to an FCA violation must be "material" to the government's payment decision, *and* the provider or contractor knows that it is material to the payment decision. Herein lies the rub with regard to noncompliance with informed consent requirements, especially during the COVID-19 pandemic.

As previously noted, there are times when obtaining complete and proper informed consent is not necessary, there are times (especially during a pandemic surge situation) when it is difficult or burdensome to do so, when physicians delegate informed consent to non-physician providers or caregivers, or when providers can only obtain partially compliant informed consent. The questions then become (1) whether or not complete and proper compliance with the informed consent CoPs and state law are material to Medicare's decision to pay claims regarding patients for whom complete and proper informed consent was not obtained or documented, and (2) whether providers have knowledge that such noncompliance is material to the payment decision.

A 2019 case alleging noncompliance with informed consent requirements formed the basis for false claims submitted to Medicare was unsealed by the court on June 5, 2020, after the federal government declined to intervene. In *United States ex rel. Zaldonis v University of Pittsburgh Medical Center et al.*,<sup>142</sup> the University of Pittsburgh Medical Center (UPMC) and related defendants are alleged to have knowingly failed to properly obtain informed consent from patients for surgeries, which led to the filing of false claims with various government agencies, including CMS. In the filing, co-plaintiff Diana Zaldonis alleges her UPMC dismissed her from her job as the lead research coordinator in UPMC's Cardiothoracic Transplantation division retaliation for reporting that surgeons improperly delegated responsibility for obtaining patient consent for surgeries. Zaldonis alleges that these physicians did not personally speak to patients but instead had resident physicians, fellows, nurse practitioners, and physician assistants obtain patient consent in violation of federal and state law, as well as UPMC policy. The court has not yet ruled on a Motion to Dismiss.<sup>143</sup>

The alleged facts of the UPMC case did not occur in a pandemic situation, but if the allegations concerning noncompliance with informed consent requirements are held to be accurate and material, this case could have implications for claims made and paid during the current pandemic, if the waiver of the record-keeping requirement that includes the necessary informed consent forms was taken to mean that informed consent is itself waived, even when reasonable to obtain it. If the government or a relator could prove that a physician could have obtained complete and proper informed consent from patients or appropriate surrogates (whether or not the patients were admitted with COVID-19, or during a surge period), but failed to do so as a pattern of practice, and the physician or healthcare organization submitted claims to CMS for medical services provided to such patients without proper informed consent, then claims for those services may constitute false claims under the FCA. At this time, federal law does not provide any blanket exception to the informed consent requirement, nor does any federal pandemic declaration, Michigan law, or Michigan Executive Order. The liability immunity provisions granted in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), federal and state pandemic declarations, and Michigan's Executive Orders may only apply

narrowly and not to any circumstance if a provider forgoes obtaining informed consent completely for all patients in all situations, or improperly delegated obtaining informed consent to other non-physicians or other caregivers. (See Immunity from Liability in section 11 below).

Again, a claim under the FCA must plead with particularity “(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.”<sup>144</sup> In a situation in which a physician or healthcare organization submitted multiple claims exhibiting a pattern of conduct (not isolated instances) to CMS for services provided to patients during the course of the declared health emergency (pandemic), and from whom complete and proper informed consent was not obtained when it was possible to do so, the argument would be that the submitting provider was fully aware that the claims were false because intentional noncompliance with the informed consent requirements was not disclosed to the government.

The general argument likely would be that both the physician and the healthcare organization were well aware of their duties to meet and maintain compliance with all laws, regulations, and Medicare program instructions, and the requirements set forth in the Medicare Integrity Manual as a result of their Medicare application certifications. For physicians, it may be further argued that such certification also included an acknowledgment and agreement that the physician understood the penalties for omitting, misrepresenting, or falsifying information in any communication to Medicare, including claims. The argument could continue in that the physician further certified understanding that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions, and that the government may recoup any existing or future overpayments made. In addition, the physician certified that in the face of all other acknowledgments of compliance duties and responsibilities owed, the physician would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and would not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Further, the argument would likely address that every licensed physician and healthcare organization is fully aware of the ethical, legal, and Medicare requirements, and the general standard of care requiring a physician to obtain complete and proper informed consent from patients (or appropriate surrogates) when possible, and properly document it in the patient’s medical record. The certification by either the healthcare organization or physician would again be used to prove that the provider was fully aware of the Medicare CoP regulations, specifically 42 CFR 482.24(c)(4)(v), regarding Medical Records Services and the requirement of obtaining complete and proper informed consent and documenting it in the patient’s medical record. The deliberate ignorance or reckless disregard for the truth or falsity of the claims made based on knowing violations



of a universally understood requirement of the practice of medicine and treatment of patients.

The scienter element may be proved through the same conduct, knowledge, and certifications, showing that the physician or healthcare organization was fully aware of the informed consent requirements, and knowingly failed to comply in situations where informed consent could be obtained.

In addition to the elements of the cause of action, the plaintiff must prove materiality pursuant to *Escobar*. Since the issuance of *Escobar*, there has been extensive litigation concerning the concept of materiality. The Supreme Court denied *certiorari* on three cases in 2019 alone, leaving intact a split in the circuits.<sup>145</sup> Many courts have addressed whether relators have sufficiently alleged materiality to survive a motion to dismiss, with cases falling for and against relators. Federal district and appellate courts continue to wrestle with application of the materiality requirement.

Materiality can be difficult to prove, but not necessarily impossible. As stated above, the first factor in the *Escobar* materiality analysis is whether compliance is a condition of payment. The provider must be enrolled in Medicare to be paid by Medicare for a claim.<sup>146</sup> To be enrolled in Medicare, the provider must complete the appropriate Medicare enrollment form.<sup>147</sup> To *complete* the appropriate Medicare form, the provider must sign the certification and acknowledgment that the provider must comply with all laws, regulations, and program instructions, and for physicians, that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions.<sup>148</sup> Medicare regulations state that to maintain Medicare enrollment a provider must certify that it meets, and continues to meet compliance with Title XVIII of the Act and applicable Medicare regulations.<sup>149</sup> The Medicare Medical Records Services CoP regulation requires that a patient's medical record include "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent."<sup>150</sup>

As for the second factor in the *Escobar* materiality analysis, the informed consent requirement is provided for in both state law and federal regulations, and more to the point, is an ethical and legal principal of medicine to protect patients and their right to self-determination and bodily integrity. (See The Basics, and attendant subsections, in section 2, and Verbal Only Consent in section 4 above). Because the failure to obtain informed consent when possible is a violation of laws, regulations, and program instructions, possibly generates a legal cause of action for the patient, one may argue that submitting claims for services performed without informed consent goes to the "essence of the bargain" of paying providers to provide appropriate, quality, and legally compliant healthcare services to covered patients.

Regarding the third factor of the *Escobar* materiality analysis, widespread violations of informed consent requirements are not generally made public, although situations such as those alleged in the UPMC case above are widely known in the healthcare industry to occur frequently in healthcare organizations across the country.<sup>151</sup>

If the government had more cases in which the practice was brought to light, it might be able to show a pattern of declining payment for noncompliance with Medicare informed consent regulations (see Verbal Only Consent in section 4 above) and violations of state informed consent law (see The Basics in section 2 above). In the absence of such cases, it may analogize to declining payment based on violations of other laws, regulations or program instructions that go to the fundamental provision of the ethical and legal practice of medicine.<sup>152</sup>

Finally, whether the government would likely refuse payment had it known of the informed consent regulatory violations is a matter that may be determined in the *Zaldonis v UPMC* case if it survives a Motion to Dismiss. There is ample proof that in other cases the government would have refused payment for similarly serious and fundamental regulatory violations related to healthcare treatment and medical practice, had it known of them at the time.<sup>153</sup> In many “failure to certify medical necessity” cases, the failure to comply with certification of medical necessity regulations has been held to be material to the government’s conditions to pay, and several other of the materiality factors.<sup>154</sup>

Also in “failure to certify medical necessity” matters under the FCA, case law demonstrates that a reasonable disagreement of physicians regarding medical necessity of a treatment is a function of professional clinical judgment, and insufficient to form the basis of “falsity” under the FCA.<sup>155</sup> Other cases contradict or are distinguishable from this holding with regard to medical necessity compliance as a basis for a false claim.<sup>156</sup>

Obtaining complete and proper informed consent when it can be obtained is not subjective or open to professional clinical judgment. When a patient has decision-making capacity, obtaining complete and proper informed consent is either necessary or not, pursuant to law and established exceptions to the informed consent requirements. Even if two physicians can reasonably differ whether a patient has decision-making capacity, these determinations should be made on an individual basis and likely will never apply to large numbers of patients, even in emergency situations.

Similarly, Michigan law provides that it is inappropriate to delegate the physician’s duty to obtain complete, proper, and documented informed consent to other non-physician providers or caregivers. It could be argued, however, that per the language and covered time frame of Michigan Executive Orders 2020-30 and 2020-61, that this may have been expanded to permit physician assistants, advanced practice nurses, nurse

anesthetists, and licensed pharmacists to provide the informed consent disclosures and obtain informed consent, if it is considered to be the provision of medical services appropriate to their education, training and experience. It turns on whether the informed consent conversation is considered part of the provision of *medical* services. If, the physicians' informed consent duty was not intended to have been delegable under the Executive Orders, then this state-law violation would be further compounded when the documentation is altered to declare that the physician engaged in the discussion with the patient or appropriate surrogate and obtained the informed consent to proceed with treatment. Such situations violate 31 USC 3729(a)(1)(A) for knowingly presenting or causing to be presented a false claim, 31 USC 3729(a)(1)(C) for conspiring to submit a false claim, and 31 USC 3729(a)(1)(B) for knowingly making, using, or causing to be made or used a false record or statement material to a false claim.

Knowingly seeking payment for claims that are based on violations of laws, regulations, and program or payer instructions, or that include false or intentionally misleading documentation used to support such claims (both to government programs or private payer organizations) for payment can also be a violation of the federal Criminal Health Care Fraud Statute<sup>157</sup> as well as other federal and state fraud and healthcare fraud statutes.<sup>158</sup>

Finally, in the United States Department of Justice's (DOJ) recent announcement that it will prioritize COVID-19-related enforcement actions, the DOJ stated that provider treatment fraud such as "obtaining patient information for COVID-19 testing and then using that information to fraudulently bill for other tests and procedures" will become a specific target of investigation.<sup>159</sup> Because other national crises have been shown to engender numerous fraud schemes, there are additional types of conduct that might fall within the new investigation priorities of the DOJ:

- "upcoding" for testing or treatments of different types or amounts than those actually provided, or "upcoding" of provider level;<sup>160</sup>
- billing for treatment or testing that is not medically necessary, especially treatment <sup>for</sup> which safety or efficacy is not evidence-based or been given Emergency Use or other authorization by the Food and Drug Administration, whether or not harm is caused;
- billing for treatment, testing, or medical supplies that do not comply with regulatory requirements;
- billing for treatment that is significantly substandard; and
- falsification of records to support any of the above.

Although investigating and pursuing healthcare providers for alleged FCA violations committed during the COVID-19 crisis may be more difficult given the nature of circumstances in healthcare facilities, and the public sentiment in support of the work done under challenging and unprecedented conditions, the DOJ will certainly find cases worthy of investigation. Despite immunity granted through the PREP Act, CARES Act, state Executive Orders (for a limited time frame), and under the Michigan Emergency Management Act (see Immunity in section 11 below) there will surely be *qui tam* and DOJ cases filed alleging care was undertaken to maximize profit with a lack of good faith and compliance with law, regulation, and standard of care.

Because of the serious nature of any widespread abrogation of patient rights and violations of law and Medicare regulations in failing to obtain complete and proper informed consent when it could be obtained, (pandemic or not), it is conceivable that the DOJ may view a case like *Zaldonis v UPMC* as a case to send a “warning shot across the bow” of all healthcare providers. The message would be to refrain from viewing informed consent as optional, something that can be cut from practice protocols, or can be delegated to non-physicians when caseloads increase and healthcare practice is complicated by unusual circumstances. COVID-19 is not the last national healthcare crisis the United States will experience, and it appears the DOJ may use this opportunity to remind healthcare providers not to become complacent with compliance or respecting patient’s rights.

## **11. Immunity from Liability**

### **A. Federal**

On March 10, 2020, pursuant to the Public Readiness and Emergency Preparedness (PREP) Act of 2005, the United States Department of Health and Human Services Secretary declared legal immunity for certain persons and entities performing qualified countermeasures to fight against COVID-19.<sup>161</sup> The declaration is retroactive to February 4, 2020.<sup>162</sup> Generally, liability immunity is provided to persons and entities that manufacture, develop, distribute, test, administer and dispense covered COVID-19 countermeasures. There is no liability immunity from loss or injury caused by, arising out of, relating to, or resulting from “willful misconduct.” Covered countermeasures include any medication, drug, antiviral, vaccine, diagnostic test, and any device used to treat, diagnose, cure, prevent or mitigate COVID-19 or a virus mutating therefrom, including any component and constituent materials of any such product. The Declaration will remain in force through October 1, 2024, but may be extended beyond that date.<sup>163</sup>

According to the federal government’s site explaining the PREP Act,<sup>164</sup> “qualified persons” potentially protected under the Act include persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories

of persons named in a declaration by the Health and Human Services Secretary.<sup>165</sup> This Act, and the Secretary's attendant declaration applies to healthcare providers and healthcare organizations that "distribute, test, administer, and dispense the COVID-19 treatments and countermeasures stated."<sup>166</sup>

The covered countermeasures are goods (drugs, vaccines, tests, devices), and possibly the services provided when distributing, testing, administering, and dispensing such things. Each of these items could (and in some instances definitely would) have attendant risks, benefits, and alternatives related to their use. Other than in emergency care situations, proposed use of these items to care for COVID-19 patients requires some informed communication and discussion either with the patient or the patient's surrogate about the risks, benefits, available alternatives, and effect of not undertaking the treatment. The patient continues to have the legal right to remain informed about their medical condition and treatment, and to make an informed decision whether or not to consent to the proposed treatment.<sup>167</sup> That right transfers to the surrogate when the patient is unable to consent.<sup>168</sup>

As noted previously, informed consent is required in various aspects of the statutory and common law, federal and state regulations and rules, accreditation standards, ethics rules, an organization's bylaws, rules, and procedures, and in other requirements. In some instances, they can be considered a standard of care. For example, compliance with licensing and scope of practice statutes, patient rights statutes, and an organization's medical staff bylaws, or other policies.<sup>169</sup> Compliance with the law of informed consent provides that an informed consent discussion related to the items covered by the Act is required (other than in an emergency care circumstance).<sup>170</sup> Failure to obtain complete and proper informed consent when it can reasonably be obtained, may become a basis for physician or organization liability. Medical malpractice is defined by failing to provide the medically accepted standard of care.<sup>171</sup> Immunity from liability may still apply in cases where informed consent was "omitted" or not properly obtained under extenuating circumstances, but it is clearly inapplicable when arising out of, relating to, or resulting from "willful misconduct."

The PREP Act defines "willful misconduct as:

[A]n act or failure to act that is taken:

- (1) intentionally to achieve a wrongful purpose;
- (2) knowingly without legal or factual justification; and
- (3) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.<sup>172</sup>

The website further advises that all three of the conditions must be proved by clear and convincing evidence. Immunity under the PREP Act will not apply to any instance in which the provider or organization intentionally denied a patient or surrogate the opportunity to grant or deny informed consent when reasonable to obtain it, with full knowledge that there was no legal or factual basis for the denial, and disregarded the knowledge that the potential risk of providing the countermeasure to the patient would probably outweigh the risk. The fact that all three conditions must be present and proven makes the chances of an informed consent basis for a medical malpractice case and the physician or provider's need for immunity from liability much less likely, although not impossible. Given the generally unprepared nature of the healthcare industry for this COVID-19 pandemic, it is not inconceivable that a patient could have been harmed in a manner that meets all three conditions, thus eliminating any immunity from liability.

For those individuals who may be injured because of failure to receive appropriate information and who were not given the opportunity to consent or decline covered COVID-19 countermeasure treatment in an informed way, the Countermeasures Injury Compensation Program (CICP) may provide relief. The CICP provides potential compensation benefits to individuals or the estates of individuals who sustain serious physical injury as the direct result of the administration or use of covered countermeasures. To be considered for benefits the individual or estate must establish by "compelling, reliable, valid, medical and scientific evidence" that the countermeasure is causally connected to the serious physical injury. This compensation program is administered by the HHS Health Resources and Services Administration.<sup>173</sup>

Note: only harm that can be proven to be the actual and proximate cause of the injury is eligible for compensation under the CICP. Proof that the COVID-19 countermeasure treatment caused harm may possibly be used as part of the proof required for a supplemental state medical malpractice claim with "reckless and indifferent" failure to obtain complete and proper informed consent as a basis for the suit. Until cases are filed and litigated under this Act, the full application of the law and the particular terminology used therein is open to interpretation and speculation.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed. The CARES Act grants liability immunity to volunteer health care providers under *both federal and state law* for acts or omissions during the course of providing health care services in response to the COVID-19 public health emergency, unless injury or death was caused by willful or criminal misconduct, gross negligence, reckless misconduct, conscious indifference or while under the influence of alcohol or intoxicating drugs.<sup>174</sup>

The CARES Act complements the PREP Act in addressing the liability immunity for volunteer healthcare providers. Those who are regularly employed to provide such

services cannot claim liability immunity under the law. Their federal law protection from liability related to the COVID-19 pandemic is solely the PREP Act, and any state law immunity protections.

The immunity exceptions stated in the CARES Act are, in essence, the same as in the PREP Act – knowing, willful, reckless, indifferent conduct resulting in harm to a patient from care provided during the COVID-19 pandemic. If a patient suffers injury or death caused by a *volunteer* physician or other care provider’s willful or criminal misconduct, gross negligence, reckless misconduct, conscious indifference, or effects of alcohol or intoxicating drugs, the volunteer physician or other provider cannot claim liability immunity for the injuries suffered by the patient. This Act seems to attempt to cover all the possible state statutory names for the same broad concept expressed in the PREP Act (willful misconduct), plus alcohol and drug intoxication-based conduct. The Act does not provide definitions for any of the immunity exception terms, but it does provide that state law applies to any circumstances involving healthcare services provided by a volunteer healthcare provider under the influence of alcohol or an intoxicating drug.<sup>175</sup>

It is unknown whether the terms “willful or criminal misconduct, gross negligence, reckless misconduct, or conscious indifference,” should be interpreted based on state law jurisprudences. If so, in *Burnett v City of Adrian* (1982)<sup>176</sup> the Michigan Supreme Court defined “willful and wanton misconduct” as:

[W]illful and wanton misconduct is made out only of the conduct alleged shows an intent to harm or, if not that, such indifference to whether harm will result as to be the equivalent of a willingness that it does.<sup>177</sup>

In *Jennings v Southwood* (1994),<sup>178</sup> the Court construed the term “willful” as used in the Michigan Emergency Medical Services Act. It approved the definition in *Burnett*, but made a further clarification:

[W]illful and wanton are distinct and logically inconsistent, so “willful and wanton” is to be read as “willful or wanton.” Willful, as *Burnett* said, requires intent to harm while wanton means the equivalent, reckless conduct without the intent to harm but with indifference as to the result.<sup>179</sup>

Michigan defines gross negligence as “[C]onduct or a failure to act that is so reckless that it demonstrates a substantial lack of concern for whether an injury will result.”<sup>180</sup>

The Michigan definition of willful relates to an intentional act, meaning an intent to cause harm, not merely an intent to act the way one chose to act. The term “wanton” is defined to cover “reckless” and “indifferent” under Michigan law, and “gross negligence” also addresses the concept of indifference. In future litigation interpreting the CARES Act,

it is possible that parties may choose to make arguments based on these definitions in Michigan law.

Under the CARES Act, a volunteer physician who fails to obtain complete and proper informed consent from a patient or surrogate when reasonable to do so, could be found by a court to be fully aware that a patient could suffer harm from the risks of the proposed treatment and be liable for the harm suffered. In simply failing to provide the patient or surrogate with an opportunity to weigh such risks against the benefits or alternatives, harm to the patient could result from the known risks. According to *Jennings*, such conduct would be “wanton misconduct” or reckless indifference to the harm that could be inflicted. Therefore, if a volunteer physician recklessly or indifferently disregards the legal and ethical duty to obtain complete and proper informed consent from a patient or the patient’s surrogate when it can be reasonably obtained, the immunity in the CARES Act may not apply.

## **B. Michigan**

The state of liability protection for healthcare workers during the pandemic is still evolving in Michigan. The following analysis reflects the state of this issue to the time of this publication.

On March 10, 2020, Governor Whitmer issued Executive Order (EO) 2020-4, declaring a state of emergency in Michigan in response to the outbreak of the novel coronavirus.

On March 29, 2020, Governor Whitmer issued EO 2020-30, which provided:

7. [C]onsistent with MCL 30.411(4), any licensed health care professional or designated health care facility that provides medical services in support of this state’s response to the COVID-19 pandemic is not liable for an injury sustained by a person by reason of those services, regardless of how or under what circumstances or by what cause those injuries are sustained, unless it is established that such injury or death was caused by the gross negligence, as defined in MCL 30.411(9), of such health care professional or designated health care facility.<sup>181</sup>

On April 1, 2020, Governor Whitmer issued EO 2020-33. This order rescinded and expanded on EO 2020-4 and declared both a state of emergency and a state of disaster across the State of Michigan under section 1 of article 5 of the Michigan Constitution of 1963, the Emergency Management Act (EMA), and the Emergency Powers of the Governor Act of 1945 (EPGA).

On April 26, 2020, Governor Whitmer issued EO 2020-61, primarily to extend the scope of licensure, supervision, and delegation provisions that were



provided in EO 2020-20. EO 2020-61 also rescinded EO 2020-30, but restated the identical liability protection provisions:

8. Consistent with MCL 30.411(4), any licensed health care professional or designated health care facility that provides medical services in support of this state's response to the COVID-19 pandemic is not liable for an injury sustained by a person by reason of those services, regardless of how or under what circumstances or by what cause those injuries are sustained, unless it is established that such injury or death was caused by the gross negligence, as defined in MCL 30.411(9), of such health care professional or designated health care facility.

On April 30, 2020, finding that COVID-19 had created emergency and disaster conditions across the State of Michigan, Governor Whitmer issued EO 2020-67 to continue the emergency declaration under the EPGA, as well as EO 2020-68 to issue new emergency and disaster declarations under the EMA.

On July 13, 2020, Governor Whitmer issued EO 2020-150. As stated in the language of EO 2020-150, those executive orders were challenged in *Michigan House of Representatives and Michigan Senate v. Whitmer*. On May 21, 2020, the Court of Claims ruled that Executive Order 2020-67 is a valid exercise of authority under the EPGA, but that Executive Order 2020-68 is not a valid exercise of authority under the EMA. Both of those rulings are being challenged on appeal.

EO 2020-150 further states that on June 18, 2020, the Governor issued EO 2020-127, again finding that the COVID-19 pandemic constitutes a disaster and emergency throughout the State of Michigan. That order constituted a state of emergency declaration under the EPGA, and to the extent the governor may declare a state of emergency and a state of disaster under the EMA when emergency and disaster conditions exist yet the legislature had declined to grant an extension request, that order also constituted a state of emergency and state of disaster declaration under that act. It stated that the EPGA also provides a sufficient legal basis for issuing the EO. In relevant part, it provides that, after declaring a state of emergency, "the governor may promulgate reasonable orders, rules, and regulations as he or she considers necessary to protect life and property or to bring the emergency situation within the affected area under control." MCL 10.31(1).

More to the point of the topic of immunity, EO 2020-150, specifically stated:

As the pressure on hospitals has eased, the importance of the broad relief afforded in Executive Orders 2020-30 and 2020-61 has waned.

Today's circumstances require a narrower form of relief than was provided in these earlier orders.

. . .

The Governor subsequently rescinded Executive Order 2020-61.

In response to the rescission of EO 2020-61 and its liability protections for healthcare workers during the COVID-19 pandemic, Senate Bill (SB) 899 was created. SB 899 sought to amend the existing language in the EMA to add further protections for healthcare workers.

The Michigan Emergency Management Act (MCL 30.411) currently states in pertinent part:

(4) A person licensed to practice medicine or osteopathic medicine and surgery or a licensed hospital, whether licensed in this or another state or by the federal government or a branch of the armed forces of the United States, or an individual listed in subsection (6), who renders services during a state of disaster declared by the governor and at the express or implied request of a state official or agency or county or local coordinator or executive body, is considered an authorized disaster relief worker or facility and is not liable for an injury sustained by a person by reason of those services, regardless of how or under what circumstances or by what cause those injuries are sustained. The immunity granted by this subsection does not apply in the event of an act or omission that is willful or gross negligence. If a civil action for malpractice is filed alleging an act or omission that is willful or gross negligence resulting in injuries, the services rendered that resulted in those injuries shall be judged according to the standards required of persons licensed in this state to perform those services.

. . .

(6) Subsections (4) and (5) apply to all of the following individuals:

(a) Any of the following, if licensed in this or another state or by the federal government or a branch of the armed forces of the United States:

(i) A registered nurse.

(ii) A practical nurse.

(iii) A nursing student acting under the supervision of a licensed nurse.

(iv) A dentist.

(v) A veterinarian.

(vi) A pharmacist.

(vii) A pharmacist intern acting under the supervision of a licensed pharmacist.

(viii) A paramedic.

(b) A medical resident undergoing training in a licensed hospital in this or another state.

...

(9) As used in this section, “gross negligence” means conduct so reckless as to demonstrate a substantial lack of concern for whether an injury results.

As noted above, for the purposes of determining if immunity is not available under the EMA, *Jennings v Southwood*,<sup>182</sup> defines the word willful, and the definition of gross negligence is provided in the statute.

SB 899 sought to amend section (4) to read:

(4) A health care provider or a health care facility, whether licensed in this or another state or by the federal government or a branch of the Armed Forces of the United States, who renders health care services during a state of disaster or state of emergency declared by the governor in support of this state’s response to the state of disaster or state of emergency is considered an authorized disaster relief worker or facility and is not liable, for the death or for an injury sustained by a person by reason of those services regardless of how or under what circumstances or by what cause those injuries are sustained or death occurs. The immunity granted by this subsection does not apply in the event of an act or omission that is willful misconduct or gross negligence or constitutes intentional and willful or criminal misconduct or intentional infliction of harm. If a civil action for malpractice is filed alleging an act or omission that is willful or gross negligence resulting in injury or death, the services rendered that resulted in those injuries or death shall be judged according to the standards required of persons licensed in this state to perform those services.

Further, SB 899 sought to add:

(7) Notwithstanding any law to the contrary, during the period which begins retroactive to March 10, 2020 and continues until January 1, 2021,

the immunity granted under subsection (4) shall extend to any death of or injury sustained by a person arising out of or as a result of any act or omission by a health care provider or health care facility while engaging in 1 or more of the following activities, which shall constitute health care services rendered in support of the state's response to the COVID-19 pandemic, unless the act or omission constitutes willful misconduct, gross negligence, intentional and willful criminal misconduct, or intentional infliction of harm:

(a) The rendering of COVID-19-related health care services by a health care provider or health care facility to an individual with presumed, suspected, or confirmed COVID-19.

(b) The arrangement, scheduling, rescheduling, canceling, or postponement of the rendering of health care services by a health care provider or health care facility, including the decision to utilize telehealth or other remote services in lieu of an in-person encounter, in reliance on or in compliance with any administrative or governmental agency, division, or department policy, rule, or directive, or any executive order or law regarding health care services provided by a health care provider or health care facility.

(c) Acts, omissions, or decisions made by a health care provider or health care facility resulting from a shortage of necessary resources, including, but not limited to, blood products, pharmaceuticals, medical equipment, or staffing.

Finally, the definition of "willful misconduct" was to be added: "Willful misconduct" means conduct or a failure to act that was intended to cause harm.

SB 899 was enrolled on July 23, 2020, presented to the Governor on July 29, 2020, and on August 10, 2020, Governor Whitmer vetoed it. Governor Whitmer stated in an official press release her reasons for vetoing the bill:

- Senate Bill 899 would make patients receiving treatment at a hospital and residents in nursing homes powerless to seek relief when they are harmed in any but the most egregious cases, regardless of the type of emergency or disaster declared by the Governor.
- The Emergency Management Act provides limited immunity from lawsuits to medical providers, activated only upon an official request, such as Governor Whitmer made at the peak of COVID-19 in Michigan. SB 899 would make this immunity automatic, even when the emergency or disaster did not call for setting aside the normal standards of care.

As of the time of publication, the current and ongoing state of liability immunity for healthcare providers during the COVID-19 pandemic lies in the existing language of section (4) of the Emergency Management Act (MCL 30.411), and applies to persons licensed to practice medicine or osteopathic medicine and surgery or a licensed hospital, whether licensed in this or another state or by the federal government or a branch of the armed forces of the United States, or an individual listed in subsection (6). It also lies in federal law as outlined above.

A claim for alleged injury resulting from failure to obtain informed consent from a patient or surrogate where such informed consent could have been reasonably obtained, or in instances related to other patient healthcare injury situations may arise in Michigan. If a lawsuit is filed, it remains to be seen whether the language of EO 2020-30 and EO 2020-61, as well as the language of the EMA in effect at the time of the alleged injury will provide immunity from liability, and whether federally provide immunity may come into play. It should be clearly understood, however, that the Executive Orders, EMA, and federal legislation do not constitute a “free pass” to avoid obtaining complete and proper informed consent where appropriate, required, and it is reasonable to do so.

***See endnotes for a helpful resource on liability and immunity during the COVID-19 pandemic.<sup>183</sup>***

## **12. Conclusion**

The informed consent requirement in the time of COVID-19 is in some instances unchanged, and in other instances is providing significant challenges for providers. Providers should go “back to the basics” when in doubt, and always act reasonably and in the best interests of their patients. It remains to be seen whether any cases emerge alleging informed consent violations in relation to medical malpractice that is claimed to have fallen outside the immunity scope. Certainly, the unprecedented nature of this situation, the unique challenges and questions that have arisen, and the circumstances that may surround the timing of the informed consent issue will affect the outcome of any such cases.

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Thanks go out to attorney Diana Lamphiere for her help with the research on this article.

<sup>2</sup> American Medical Association, *Informed Consent*, <<https://www.ama-assn.org/delivering-care/ethics/informed-consent>> (accessed, August 14, 2020); Bernat & Peterson, *Patient-Centered Informed Consent in Surgical Practice*, Arch Surg. 2006;141(1):86-92.

<sup>3</sup> *Id.* The phrase “informed consent” was coined in *Salgo v Leland Stanford etc. Bd. Trustees*, 154 Cal App 2d at 560; 317 P2d at 170 (1957).

<sup>4</sup> *Cruzan v Director, Missouri Dep’t of Health*, 497 US 261; 110 S Ct 2841; 111 L Ed 2d 224 (1990); Beauchamp & Childress, *Principles of Biomedical Ethics* (7<sup>th</sup> ed), (New York, NY: Oxford University Press, 2012).

<sup>5</sup> *Union Pacific Railway Co v Botsford*, 141 US 250, 251; 11 S C 1000; 35 L Ed 734 (1891).

<sup>6</sup> *Schloendorff v Society of New York Hospital*, 211 NY 125, 12930; 105 NE 92, 93 (Ny Ct App, 1914).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*, citing *Pratt v Davis*, 224 Ill 300; 79 NE 562 (1906); *Mohr v Williams*, 95 Minn 261; 104 NW 12 (1905).

<sup>9</sup> *Salgo v Leland Stanford Jr University Board of Trustees*, 317 P 2d 170 (Cal Dist Ct App 1957).

<sup>10</sup> *Lucas v Awaad*, 299 Mich App 345, 361; 830 N W 2d 141, 150 (2013); MCL 333.20201; MCL 333.5654.

<sup>11</sup> *Id.*

<sup>12</sup> *Davis v Hoffman*, 972 F Supp 308 (ED Pa, 1997).

<sup>13</sup> 1 Restatement 3d, Agency, *Duties of Principal and Agent to Each Other*, 8.01(a), comments *b* and *c*, p 4.

<sup>14</sup> 1 Restatement 3d, Agency, *Duties of Principal and Agent to Each Other*, 8.01, p 4; 3.15 comment *d*.

<sup>15</sup> See, e.g., *Blanchard v Kellum*, 975 SW2d 522, 524 (Tenn, 1998) (discussing unauthorized dental extractions as a battery claim).

<sup>16</sup> Furrow et al., *Health Law* (7th ed), p 121 (St. Paul, MN: West Academic Publishing, 2013).

<sup>17</sup> *Banks v Wittenberg*, 82 Mich App 274, 279; 266 NW2d 788, 791 (1978); *Lounsbury v Capel*, 836 P 2d 188 (Utah Ct App, 1992).

<sup>18</sup> Knifed, Lison, Mason, Bernstein, *Patients’ Perception of the Informed Consent Process for Neurooncology Clinical Trials*, Neuro Oncol. 2008 Jun; 10(3): 348–354; Hammaker &, Knadig, *Health Care Ethics and the Law*, (Burlington, MA: Jones and Bartlett Learning, 2017).

<sup>19</sup> *Cruzan by Cruzan v Harmon*, 760 SW2d 408, 417; 57 USLW 2324 (1988); *Kaimowitz v Michigan*, DMH 1 MDLR 147 (1976); *Reif v Weinberger*, 372 F Supp 1196 ( DC, 1974); Beauchamp & Childress, *Principles of Biomedical Ethics* (7<sup>th</sup> ed), (New York, NY: Oxford University Press, 2012).

<sup>20</sup> *Lincoln v Gupta*, 142 Mich App 615, 625; 370 NW2d 312, 318 (1985).

<sup>21</sup> Patient Protection and Affordable Care Act 1557, 42 USC 18116 ; American Medical Association, *Informed Consent*, 8.08, <<https://www.ama-assn.org/delivering-care/ethics/informed-consent>> (accessed August 14, 2020); Penn State College of Medicine Ethics Committee, *Informed Consent*, <<https://sites.psu.edu/humanities/files/2016/09/Informed-consent-9-2016-1en2vbp.pdf>> (accessed August 14, 2020).

<sup>22</sup> Laurie, Harmon & Porter. *Mason & McCall Smith’s Law and Medical Ethics*, (10<sup>th</sup> ed), 4.37, p 83 (Oxford, UK: Oxford University Press, 2016) ; MCL 330.1489; *Large v Superior Court of Arizona*, 714 P2d 399 (1986).

<sup>23</sup> First recognized in *O’Brien v Cunard Steam Ship Co*, 28 NE 266 (Mass, 1891).

<sup>24</sup> First recognized in *Darrah v Kite*, 32 A2d 108 (New York, 1969).

<sup>25</sup> First recognized in *O’Brien v Cunard Steam Ship Co*, 28 NE 266 (Mass, 1891).

<sup>26</sup> *Cruzan v Director, Missouri Dep’t of Health*, 497 US 261, 270; 110 S Ct 2841; 111 L Ed 2d 224 (1990).

<sup>27</sup> *Mohr v Williams*, 95 Minn 261, 269-70; 104 NW 12, 15 (1905).

<sup>28</sup> First recognized in *O’Brien v Cunard Steam Ship Co*, 28 NE 266 (Mass, 1891).

<sup>29</sup> *Cobbs v Grant*, 8 Cal 3d at 243; 502 P2d at 10; 104 Cal Rptr at 514 (1972).

<sup>30</sup> *Canterbury v Spence*, 464 F2d 772, 788-789 (DC Cir 1972). Custom and practice also require that the physician attempt to obtain a relative’s consent if possible.

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- <sup>31</sup> *Luka v Lowrie*, 171 Mich 122; 136 NW 1106 (1912).
- <sup>32</sup> Watson, *An Approach to Customary Law*, 1984 U Ill L Rev, 561-562.
- <sup>33</sup> *Id.*
- <sup>34</sup> *Jacobson v Massachusetts*, 197 US 11, 27-38 (1905).
- <sup>35</sup> MCL 691.1501.
- <sup>36</sup> *Carbonnell v Bluhm*, 114 Mich App 216, 224; 318 NW2d 659, 663 (1982).
- <sup>37</sup> *Canterbury v Spence*, 464 F2d 772, 788-789 (DC Cir 1972). Custom and practice also require that the physician attempt to obtain a relative's consent if possible.
- <sup>38</sup> *Id.*
- <sup>39</sup> MCL 333.20201; MCL 333.5654; MCL 333.17015; MCL 333.17020.
- <sup>40</sup> *Carbonnell v Bluhm*, 114 Mich App 216, 224; 318 NW2d 659, 663 (1982); *Nixdorf v Hicken*, 612 P2d 348 (Utah 1980).
- <sup>41</sup> *Id.*; *White v Leimbach*, 131 Ohio St 3d 21, 26-27; 959 NE2d 1033, 1039 (2011).
- <sup>42</sup> *Carbonnell v Bluhm*, 114 Mich App 216, 224; 318 NW2d 659, 663 (1982).
- <sup>43</sup> American Medical Association, *Report of the Council on Medical Service Regarding Shared Decision Making* (2010), <<https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-service/a10-cms-shared-decision-making.pdf>> (accessed August 14, 2020).
- <sup>44</sup> Office of the National Coordinator for Health Information Technology, *Fact Sheet*, 2013, <[https://www.healthit.gov/sites/default/files/nlc\\_shared\\_decision\\_making\\_fact\\_sheet.pdf](https://www.healthit.gov/sites/default/files/nlc_shared_decision_making_fact_sheet.pdf)> (accessed August 14, 2020).
- <sup>45</sup> Childress and Childress, *What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?* (2020) <<https://journalofethics.ama-assn.org/article/what-does-evolution-informed-consent-shared-decision-making-teach-us-about-authority-health-care/2020-05>> (accessed August 14, 2020).
- <sup>46</sup> *Howard v University of Medicine & Dentistry of New Jersey*, 800 A2d 73 (NJ, 2002); *Johnson v Kokemoor*, 545 NW2d 495 (Wis, 1996); *Hidding v Williams*, 578 S2d 1192 (La Ct App, 1991); *Faya v Almaraz*, 620 A2d 327 (Md, 1993); *DAB v Brown*, 570 NW2d 168 (Minn Ct App, 1997); *Moore v Regents of the University of California*, 793 P2d 479 (Cal, 1990); *Shea v Esensten*, 208 F3d 712 (8th Cir, 2000).
- <sup>47</sup> Pope, *Informed Consent and the Oncologist: Legal Duties to Discuss Costs of Treatment*, The American Society of Clinical Oncologists Post, <<https://www.ascopost.com/issues/november-25-2017/informed-consent-and-the-oncologist-legal-duties-to-discuss-costs-of-treatment/>> (accessed August 14, 2020).
- <sup>48</sup> MCL 333.16213; MCL 333.20175.
- <sup>49</sup> American Medical Association, *Informed Consent*, <<https://www.ama-assn.org/delivering-care/ethics/informed-consent>> (accessed August 14, 2020).
- <sup>50</sup> *Id.*
- <sup>51</sup> *Id.*
- <sup>52</sup> *Cornfeldt v Tongen*, 262 NW2d 684, 700 (Minn, 1977).
- <sup>53</sup> Civetta, Taylor & Kirby, *Critical Care* (4<sup>th</sup> ed), Chapter 5: Informed Consent, p 49 (Philadelphia, PA: Lippincott, Williams & Wilkins, 1997).
- <sup>54</sup> MCL 333.5653; MCL 333.5654.
- <sup>55</sup> *In re Martin*, 450 Mich 204, 218; 538 NW2d 399, 406 (1995).
- <sup>56</sup> Watson, *An Approach to Customary Law*, 1984 U Ill L Rev, 561-562.
- <sup>57</sup> MCL 333.5655.
- <sup>58</sup> MCL 700.5507(2).
- <sup>59</sup> MCL 700.5512(2).
- <sup>60</sup> MCL 700.5506–700.5520.
- <sup>61</sup> MCL 333.1051, *et seq.*
- <sup>62</sup> MCL 700.5506 –700.5520.
- <sup>63</sup> MCL 333.10101– MCL 333.10123.

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<sup>64</sup> MCL 700.5506; MCL 333.1054 and MCL 333.1056; MCL 333.10101–333.10123.

<sup>65</sup> *Martin v Martin (In re Martin)*, 450 Mich 204; 538 NW2d 399 (1995), *cert den'd* 516 US 1113 (1996).

<sup>66</sup> Castillo, Williams, Hooper, Sabatino, Weithorn, Sudore, *Lost in Translation: The Unintended Consequences of Advance Directive Law on Clinical Care*, *Annals of Internal Med.* 2011 Jan. <<https://www.acpjournals.org/doi/10.7326/0003-4819-154-2-201101180-00012> > (accessed August 14, 2020).

<sup>67</sup> MCL 700.5506– 700.5520.

<sup>68</sup> MCL 700.5506–700.5507.

<sup>69</sup> According to the decision in *Martin v Martin (In re Martin)*, 450 Mich 204; 538 NW2d 399 (1995), *cert den'd* 516 US 1113 (1996), the designation should include all such statements describing the patient’s wishes.

<sup>70</sup> *Id.*; the forms for DNR Orders must include the language set forth in MCL 333.1054 and MCL 333.1056. A patient advocate may also sign the Order pursuant to MCL 700.5506(1) and MCL 333.1053.

<sup>71</sup> Michigan DNR form: <[https://www.michigan.gov/documents/mdch/Do\\_not\\_resuscitate.policy\\_298357\\_7.pdf](https://www.michigan.gov/documents/mdch/Do_not_resuscitate.policy_298357_7.pdf)> (accessed August 14, 2020).

<sup>72</sup> MCL 700.5506 – MCL 700.5507.

<sup>73</sup> MCL 700.5506(3) and (4).

<sup>74</sup> MCL 700.5501(2).

<sup>75</sup> MCL 700.5506(3) and (4).

<sup>76</sup> MCL 700.5506(3).

<sup>77</sup> MCL 700.5507.

<sup>78</sup> MCL 700.5506(3).

<sup>79</sup> State of Michigan, *Executive Order 2020-41 (COVID-19)*, <[https://www.michigan.gov/whitmer/0,9309,7-387-90499\\_90705-525178--,00.html](https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-525178--,00.html) > (accessed August 14, 2020).

<sup>80</sup> *For example*, MCL 333.20201(2)(e), (f), (h), (j), (k), (n), (o); MCL 333.17014–17015; MCL 333.5133; MCL 333.17020; MCL 333.5654(b); MCL 333.16284; MCL 333.16213; MCL 330.1716; 42 USC 282(i) and (j)(1)(A).

<sup>81</sup> *For example*, Medicare Conditions of Participation 42 CFR 482.11; 42 CFR 482.13; 42 CFR 482.51; 42 CFR 441.257; 42 CFR 2.31; 42 CFR 485.608; 42 CFR 50.204; 42 CFR 482.24(c)(4)(v); 42 CFR 485.638; 42 CFR 485.639; 45 CFR 46.116; 16 CFR 1028.116; 21 CFR 50.20; 21 CFR 50.25; 21 CFR 50.27; 21 CFR 56.109(c); CMS State Operations Manual App A, Interpretive Guidelines for Hospitals at A-0131, A-0132, A-0351, A-0466, A-0467, A-0955; MDOC Policy 03.04.105.

<sup>82</sup> *For example*, The Joint Commission (TJC): RC 02.01.01; RI 01.01.01; RI 02.01.01; RI 01.03.01; RI 01.05.01; LD 04.01.01; Healthcare Facilities Accreditation Program (HFAP): Std 10.01.06; DNV Healthcare - National integrated Accreditation for Healthcare (DNV-NIAHO) PR-4.

<sup>83</sup> *For example*, Michigan Medicine Medical Staff Bylaws, Rule 5.2; Henry Ford Health System Code of Conduct; McLaren Healthcare Research Policies and Procedures – Informed Consent; Wayne State University School of Medicine MD Handbook and Policies P-6, EPA-11.

<sup>84</sup> *For example*, The American Medical Association (AMA) Code of Medical Ethics, Principle 2, Op 2.1.1; The American College of Obstetricians and Gynecologists (ACOG), Ethics Committee Opinion 439; American Society of Plastic Surgeons (ASPS) Code of Ethics, Statement of Principle on Informed Consent; American Academy of Family Physicians (AAFP) Medical Ethics, The Four Principles of Bioethics – Informed Consent; American College of Cardiology (ACC) Code of Ethics, Rule 1.7; American College of Surgeons (ACS) Statement of Principles, 2A; American Association of Physician Assistants (AAPA) Guidelines for Ethical Conduct, Informed Consent.

<sup>85</sup> *Reasonableness*, Black’s Law Dictionary, (11th ed 2019).

<sup>86</sup> M Civ JI 30.01.

<sup>87</sup> *Anatomy of a Michigan Medical Malpractice Case* (2019) <<https://www.sommerspc.com/wp-content/uploads/Anatomy-of-a-Med-Mal-Case-2019.pdf>> (accessed August 14, 2020).

<sup>88</sup> **Helpful Resource:**

- From *The University of Arkansas for Medical Sciences*: <<https://irb.uams.edu/2020/04/01/consent-process-adaptations-in-the-time-of-covid-19/>>

<sup>89</sup> Donald Rumsfeld, February 12, 2002.

<sup>90</sup> Definition and purpose of EUAs, available at <<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>> (accessed August 14, 2020). Copyright 2020. State Bar of Michigan Health Care Law Section and Julie Janeway. All Rights Reserved.



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<sup>91</sup> *Carbonnell v Bluhm*, 114 Mich App 216, 224; 318 NW2d 659, 663 (1982).

<sup>92</sup> **Helpful Resource:**

- From *University of Chicago Dept. of Surgery, Annals of Surgery - The Unknown Unknowns: Surgical Consent During the COVID-19 Pandemic*. <[https://journals.lww.com/annalsurgery/Citation/9000/Unknown\\_Unknowns\\_\\_Surgical\\_Consent\\_during\\_the.94579.aspx](https://journals.lww.com/annalsurgery/Citation/9000/Unknown_Unknowns__Surgical_Consent_during_the.94579.aspx)>

<sup>93</sup> Centers for Medicare and Medicaid Services, State Operations Manual <<https://www.cms.gov/Regulations-and-Guidance/Guidance/transmittals/downloads/R75SOMA.pdf>> (accessed August 14, 2020).

<sup>94</sup> CMS News Alert (March 30, 2020) and CMS News Alert (July 30, 2020), p.12, available at <<https://www.cms.gov/files/document/covid-hospitals.pdf>> (accessed August 14, 2020).

<sup>95</sup> Definition of Rule Out Area: an area that has been specifically designated for evaluation of specific patients to determine or rule out whether they meet a particular set of disease, treatment, or other medical criteria. Emergency departments often serve this purpose in hospitals, but others may be established in times of public health emergency or mass casualty incidents and the like.

<sup>96</sup> American Society for Healthcare Risk Management, *ASHRM Exchange Digest*, April 2020, Dana Farber/Harvard Cancer Center.

<sup>97</sup> **Helpful Resource:**

- From *The University of Michigan Medical School* regarding clinical research consent (and the use of SignNow e-signature software): <<https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmed/informed-consent-assent-templates>>

<sup>98</sup> Patient Protection and Affordable Care Act 1557, 42 USC 18116.

<sup>99</sup> *Lau v Nichols*, 414 US 563; 94 S Ct 786; 39 L Ed 2d 1 (1974).

<sup>100</sup> The U.S. Department of Health and Human Services, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, <<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html>>

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> Hall, Prochazka & Fink, *Informed Consent for Clinical Treatment*, 2012 Mar 20; 184(5): 533–540.

<sup>107</sup> Stanford University, *Medical Ethics* 101, <<https://web.stanford.edu/class/siw198q/websites/reprotech/New%20Ways%20of%20Making%20Babies/EthicVo.c.htm>> (accessed August 14, 2020).

<sup>108</sup> **Helpful Resources:**

- From *The Health Literacy Project*, providing Covid-19 information in a significant number of languages: <<https://covid19healthliteracyproject.com/>>
- 45 CFR 92: *Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Health Programs or Activities Administered by the Department of Health and Human Services or Entities Established Under Title I of The Patient Protection And Affordable Care Act*.
- From *The Dept. of Health and Human Services – Office for Civil Rights*: <<https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html>>

<sup>109</sup> California Dental Association, *Covid-19 Information and FAQs*, <<https://www.cda.org/Home/News-and-Events/COVID-19/Coronavirus-FAQs-and-Resources/informed-consent-and-emergency-treatment>> (accessed August 14, 2020).

<sup>110</sup> **Helpful Resources:**

- From *The American Society of Plastic Surgeons*, Covid-19 Acknowledgment and Informed Consent for Elective Procedure form document: <<https://www.plasticsurgery.org/documents/medical-professionals/COVID19-Informed-Consent.pdf>>
- From *HR for Health (hrforhealth.com)*, COVID-19 Emergency Treatment - Patient Consent Form: <<https://cdn2.hubspot.net/hubfs/5014795/COVID-19/COVID-19%20Emergency%20Treatment%20Consent%20Patient.pdf>>
- From *The American Psychological Association*, Sample Informed Consent Form for resuming in-person services: <<https://www.apaservices.org/practice/clinic/covid-19-informed-consent>>
- From *The Doctors Company*:  
<<https://www.thedoctors.com/articles/informed-consent-for-covid-19-risks-frequently-asked-questions/>>  
<<https://www.thedoctors.com/articles/elective-surgery-informed-consent-and-shared-decision-making-during-covid-19/>>

<sup>111</sup> **Helpful Resources:**

- From *The University of Michigan Medical School* regarding clinical research consent: <<https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmd/informed-consent-assent-templates>>
- From *The Mayo Clinic*, Covid-19 Expanded Access Program, Covid-19 Convalescent Plasma Research Study Protocols and Informed Consent: <<https://www.uscovidplasma.org/>>
- From *Gilead*, regarding Remdesivir Informed Consent: <<https://www.research.va.gov/programs/orppe/education/webinars/Gilead-Informed-Consent-COVID19.docx>>
- From *WCG*, Covid-19 Research FAQs including Informed Consent updates: <<https://www.wcgclinical.com/covid-19/faqs/#consent>>
- From *The Society of Critical Care Medicine*, Waiver of Informed Consent for Emergency Research under the Revised “Common Rule”: <<https://www.sccm.org/Communications/Critical-Connections/Archives/2018/Waiver-of-Informed-Consent-in-Emergency-Situations>>
- From *The U.S. Department of Health and Human Services, Office for Human Protections*, regarding the Revised Common Rule: <<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>>
- From *The U.S. Department of Health and Human Services*, IRB Guidance on Informed Consent: <[https://www.michigan.gov/mdhhs/0,5885,7-339-71551\\_2945\\_32550-140356--,00.html](https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_32550-140356--,00.html)>

<sup>112</sup> Center for Connected Health Policy, *Informed Consent*, <<https://www.cchpca.org/telehealth-policy/informed-consent>> (accessed August 14, 2020).

<sup>113</sup> **Helpful Resources:**

- From *The Doctors Company*, Telehealth Informed Consent Form with optional national health emergency language: <<https://www.thedoctors.com/siteassets/pdfs/risk-management/informed-consent-forms/telehealth-informed-consent.pdf>>
- From *The American Society of Hematology*, Covid-19 and Telemedicine, including verbal consent information, documentation tips, and visit checklist: <<https://www.hematology.org/covid-19/covid-19-and-telemedicine>>
- From *The American Society of Plastic Surgeons*, Telemedicine Informed Consent for patients new to telemedicine visits: <<https://www.plasticsurgery.org/documents/medical-professionals/Telemedicine-Informed-Consent.pdf>>

<sup>114</sup> Keris, Physicians News Digest: *EMR Documentation Issues During the COVID-19 Pandemic* (April 2020), available at <<https://physiciansnews.com/2020/04/20/emr-documentation-issues-during-the-covid-19-pandemic/>> (accessed August 14, 2020).

<sup>115</sup> **Helpful Resource:**

- 21 CFR 50.20; 50.25; 50.27; 56.109(c): General requirements for documenting informed consent in research programs.

<sup>116</sup> *CMS Corona Waivers and Flexibilities for Healthcare Providers*, available at <<https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waiversCMS>> (accessed August 14, 2020).

<sup>117</sup> CMS, Medicare Program Integrity Manual 15.1.1 (2020).

<sup>118</sup> 42 CFR 424.510.

<sup>119</sup> CMS Form 855A, Medical Enrollment Application for Institutional Providers (July 2011); almost identical language in CMS Form 855B for Clinics, Group Practices, and Certain Other Suppliers (July 2011).

<sup>120</sup> 42 CFR 424.516(a)(1).

<sup>121</sup> CMS State Operations Manual, App'x A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, A-0466, Interpretive Guidelines 482.24(c)(4)(v), at 287 (2018) (Rev. 95, effective June 7, 2013).

<sup>122</sup> US Dep't of Health & Human Svs, Office for Human Research Protections, *Federal Policy for the Protection of Human Subjects ('Common Rule')* available at <<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>> (accessed August 14, 2020).

<sup>123</sup> 31 USC 3729-3733.

<sup>124</sup> 31 USC 3729(a)(1)(A).

<sup>125</sup> 31 USC 3729(a)(1)(C).

<sup>126</sup> 31 USC 3729(a)(1)(B).

<sup>127</sup> 31 USC 3729(b)(1)(A).

<sup>128</sup> 31 USC 3729(b)(1)(B).

<sup>129</sup> 31 USC 3729(b)(4).

<sup>130</sup> 31 USC 3729–3733.

<sup>131</sup> *U.S. ex rel. Campie v Gilead Sciences, Inc.*, 862 F3d 890, 899 (9th Cir 2017).

<sup>132</sup> Fed R Civ Proc 9(b).

<sup>133</sup> 579 US \_\_\_\_; 136 S Ct 1989(2016).

<sup>134</sup> 136 S Ct 1989, 1999-2000 (2016).

<sup>135</sup> 136 S Ct 1989, 2001 (2016).

<sup>136</sup> 136 S Ct 1989, 1996 (2016).

<sup>137</sup> 136 S Ct 1989, 1995 (2016).

<sup>138</sup> 136 S Ct 1989, 1996 (2016).

<sup>139</sup> 136 S Ct 1989, 1994 (2016).

<sup>140</sup> 136 S Ct 1989, 2003 (2016).

<sup>141</sup> 136 S Ct 1989, 2003 (2016).

<sup>142</sup> Case No. 2:19-cv-01220-MJH (WD Pa Sept 24, 2019), [https://www.pacermonitor.com/public/case/34559935/UNITED\\_STATES\\_OF\\_AMERICA\\_et\\_al\\_v\\_UNIVERSITY\\_OF\\_PITTSBURGH\\_MEDICAL\\_CENTER\\_et\\_al](https://www.pacermonitor.com/public/case/34559935/UNITED_STATES_OF_AMERICA_et_al_v_UNIVERSITY_OF_PITTSBURGH_MEDICAL_CENTER_et_al)

<sup>143</sup> Steve Twedt, *Lawsuit Claims UPMC Doctors did not get Informed Patient Consent*, Pittsburgh Post-Gazette (August 14, 2020) available at <<https://www.post-gazette.com/business/healthcare-business/2020/07/06/Lawsuit-UPMC-doctors-informed-patient-consent-CMS/stories/202007060087>> (accessed August 14, 2020).

<sup>144</sup> *U.S. ex rel. Campie v Gilead Sciences, Inc.*, 862 F3d 890, 899 (9th Cir 2017).

<sup>145</sup> *U.S. ex rel. Prather v Brookdale Senior Living Communities, Inc.*, 892 F3d 822 (6th Cir June 11, 2018); *U.S. ex rel. Campie v Gilead Sciences, Inc.*, 862 F3d 890 (9th Cir 2017); and *U.S. ex rel. Harman v Trinity Industries*, 872 F3d 645 (5th Cir 2017).

<sup>146</sup> 42 CFR 424.510.

<sup>147</sup> 42 CFR 424.510; CMS Enrollment Forms 855A, 855B, or 855i.

<sup>148</sup> CMS Enrollment Forms 855A, 855B, or 855i.

<sup>149</sup> 42 CFR 424.516(a)(1).

<sup>150</sup> 42 CFR 482.24(c)(4)(v).

- <sup>151</sup> Mark Crane, *Legal Risks of Delegating Informed Consent to an NP or PA*, Medscape (November 30, 2017), <https://www.medscape.com/viewarticle/887074>; J.P. Shand and Clarence Watson, *Delegation of Physician Responsibility in Obtaining Informed Consent*, The Journal of the American Academy of Psychiatry and the Law (June 2018), <http://jaapl.org/content/46/2/254>; Robert Morton, *Informed Consent: Substance and Signature*, The Doctors Company (May 5, 2020), <https://www.thedoctors.com/articles/informed-consent-substance-and-signature/>.
- <sup>152</sup> *U.S. ex rel. David Nutter, M.D., and David Nutter, M.D., individually, v. Sherif F. Khalil, M.D., Beaver Medical group, L.P., The Beaver Medical Clinic, Inc., Epic Management, L.P., and Epic Management, Inc.*, No. CVC17-02035-PSG-KKX (CD Cal); *U.S. ex rel. Medrano and Lopez v Diabetic Care Rx LLC, d/b/a Patient Care America, et al.*, No. 15-CV-62617 (SD Fla); *U.S., et al., ex rel. Smith and Rogers v Tom S. Chang, M.D., et al.*, No. 13-CV-3772-DMG (CD Cal); *U.S. ex rel. Markelson v Lenox Hill Hospital et al.*, No. 1:17-cv-07986 (SDNY Nov. 8, 2019); *Godecke v Kinetic Concepts, Inc.*, 937 F3d 1201 (9th Cir 2019).
- <sup>153</sup> *U.S. ex rel. Lemon v Nurses to Go, Inc.*, 924 F3d 155 (5th Cir 2019); *U.S. ex rel. Prather v Brookdale Senior Living Communities, Inc.*, 892 F3d 822 (2018).
- <sup>154</sup> *U.S. v Paulus*, 894 F3d 267 (6th Cir 2018); *U.S. ex rel. Polukoff v St. Mark's Hospital*, 895 F3d 730 (10th Cir 2018); *U.S. ex rel. Clarke, et al. v Aegerion Pharmaceuticals, Inc., et al.*, No. 13-CV-11785 (D Mass); *U.S. ex rel. McGuire v Millennium Laboratories, Inc.*, No. 12-cv-10132 (D Mass).
- <sup>155</sup> *U.S. v AseraCare Inc.*, 938 F3d 1278 (11th Cir 2019).
- <sup>156</sup> *U.S. v Paulus*, 894 F3d 267 (6th Cir 2018); *U.S. ex rel. Polukoff v St. Mark's Hospital*, 895 F.3d 730 (10th Cir 2018); and *U.S. v Care Alternatives*, 2020 WL 1038083, at \*8 (3rd Cir Mar 4, 2020).
- <sup>157</sup> 18 USC 1345-1347.
- <sup>158</sup> State Bar of Michigan, Health Care Law Section, *Healthcare Fraud and Abuse Manual* (2009) (for general statutory citations), [https://higherlogicdownload.s3.amazonaws.com/MICHBAR/f8a8a213-d7d6-49c4-bdff-e6c7a728e471/UploadedImages/pdfs/fraud\\_abuse.pdf](https://higherlogicdownload.s3.amazonaws.com/MICHBAR/f8a8a213-d7d6-49c4-bdff-e6c7a728e471/UploadedImages/pdfs/fraud_abuse.pdf).
- <sup>159</sup> U.S. Dep't of Just., *Memorandum from Att'y Gen. William P. Barr* (Mar 16, 2020), <https://www.justice.gov/ag/page/file/1258676/download>; Press Release, U.S. Dep't of Just., Off. of Pub. Aff., *Att'y Gen. William P. Barr Urges American Public to Report COVID-19 Fraud* (Mar 20, 2020), <https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud>.
- <sup>160</sup> Press Release, U.S. Dep't of Just., Off. of Pub. Aff., *Healthcare Service Provider to Pay \$60 Million to Settle Medicare and Medicaid False Claims Act Allegations* (Feb 6, 2017), <https://www.justice.gov/opa/pr/healthcare-service-provider-pay-60-million-settle-medicare-and-medicaid-false-claims-act>.
- <sup>161</sup> Federal Register, <<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>>
- <sup>162</sup> *Id.*
- <sup>163</sup> *Id.*
- <sup>164</sup> PHE.gov, *PREP Act Q&As*, <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx> (accessed August 14, 2020); 42 USC 247d-6d and 42 USC 247d-6e.
- <sup>165</sup> *Id.*
- <sup>166</sup> *Id.*
- <sup>167</sup> *Lucas v Awaad*, 299 Mich App 345, 361; 830 N W 2d 141, 150 (2013); MCL 333.20201; MCL 333.5654.
- <sup>168</sup> Civetta, Taylor & Kirby, *Critical Care* (4<sup>th</sup> ed), Chapter 5: Informed Consent, p 49 (Philadelphia, PA: Lippincott, Williams & Wilkins, 1997); MCL 333.5653; MCL 333.5654.
- <sup>169</sup> MCL 333.17015; MCL 333.20201; Michigan Medicine Medical Staff Bylaws, Rule 5.2; McLaren Healthcare Research Policies and Procedures – Informed Consent; American College of Cardiology (ACC) Code of Ethics, Rule 1.7.
- <sup>170</sup> MCL 333.20201; MCL 333.5654; MCL 333.17015; MCL 333.17020.
- <sup>171</sup> Black's Law Dictionary, 11<sup>th</sup> Ed.
- <sup>172</sup> PHE.gov, *PREP Act Q&As*, available at <<https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>> (accessed August 14, 2020); 42 USC 247d-6d and 42 USC 247d-6e.
- <sup>173</sup> HRSA.gov, *About C/ICP*, available at <<https://www.hrsa.gov/cicp/about/index.html>> (accessed August 14, 2020).

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<sup>174</sup> Section 4216 of Public Law 116-136 (03/27/2020); The American Medical Association, *Liability Protections for Health Care Professionals During COVID-19*, available at <<https://www.ama-assn.org/practice-management/sustainability/liability-protections-health-care-professionals-during-covid-19>> (accessed August 14 , 2020).

<sup>175</sup> PL 116-136 Section 1101.

<sup>176</sup> *Burnett v City of Adrian*, 414 Mich 448; 326 NW2d 810 (1982); M Civ JI 14.12.

<sup>177</sup> *Id.* at 455.

<sup>178</sup> *Jennings v Southwood*, 446 Mich 125; 521 NW2d 230 (1994); M Civ JI 14.11.

<sup>179</sup> *Id.*

<sup>180</sup> M Civ JI 14.10.

<sup>181</sup> State of Michigan, *Executive Order 2020-30 (COVID-19)*, <[https://www.michigan.gov/whitmer/0,9309,7-387-90499\\_90705-523481--,00.html](https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-523481--,00.html)> (accessed August 14, 2020).

<sup>182</sup> 446 Mich 125; 521 NW2d 230 (1994); M Civ JI 14.11.

<sup>183</sup> **Helpful Resource:**

- From *Dana Farber/Harvard Cancer Center*, Additional Consent Language for COVID-19 Research, Liability Immunity/Limitation on Right to Sue: <<https://www.dfhcc.harvard.edu/news/detail/story/additional-consent-language-for-covid-19-research/>> (accessed August 14, 2020).