

The Regulation of Telehealth / Online Therapy and Informed Consent

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I have previously written about various functions of regulatory boards (e.g., their authority and power to pass regulations, and the limitations of that authority) as well as a variety of issues related to “online therapy” and “telemedicine.” I have also written about informed consent – drawing a distinction between the doctrine of “informed consent” and disclosures that may be required by state law or by regulations promulgated by a licensing board. These three topics come together here as a result of recently enacted (effective July 1, 2016) “telehealth” regulations promulgated by the licensing board for professional clinical counselors, educational psychologists, clinical social workers, and marriage and family therapists in California. While this article addresses California law and regulation, it may prove helpful or instructive for those in other states who have an interest in this burgeoning aspect of health care, and for those who may desire to influence emerging public policy.

The first comprehensive telehealth/telemedicine law in the nation was enacted in California in the mid-1990s. Section 2290.5 of the California Business and Professions Code deals with telehealth in a variety of respects for licensed health care (healing arts) practitioners. This statute has been amended over the years to reflect the thinking of the Legislature and other policymakers with respect to the delivery of health care via telehealth. Increasingly, it has been the view of policymakers that unnecessary or arbitrary barriers to accessing the delivery of healthcare electronically should be eliminated or minimized. It is also the view that unnecessary or arbitrary barriers which prevent the integration of telehealth into California’s health care delivery system must be removed. Much has changed over the past decade or more. Treatment via telehealth is no longer viewed by policymakers and others as particularly risky or inherently dangerous, nor is it viewed as experimental.

With respect to the issue of “informed consent,” earlier iterations of the telemedicine law required that prior to the delivery of health care via “telemedicine,” the health care practitioner was required to obtain the verbal and written informed consent from the patient. The statute specified the information that had to be provided to the patient both verbally and in writing, and it required a written statement, signed by the patient, indicating that the patient understood the written information provided and that the information was discussed with the health care practitioner. A key part of the information required to be provided, and clearly the hallmark of the doctrine of informed consent, was “a description of the potential risks, consequences, and benefits of telemedicine.”

About five years ago, legislation was enacted that amended Section 2290.5 of the Business and Professions Code by, among other things, 1) repealing the provision requiring informed consent and 2)

repealing the requirement to inform the patient of the potential risks, consequences, and benefits of telehealth. There was recognition by the Legislature that while there were differences between traditional face to face treatment and treatment via telehealth, there was nothing inherently dangerous, risky, or experimental about the delivery of healthcare via telehealth. The doctrine of informed consent typically requires disclosures of “all significant perils,” not mere differences. Thus, the necessity of the former mandate of informed consent, where the potential risks, consequences, and benefits had to be disclosed, was determined to be unnecessary. The amended law only required consent.

Essentially, the practitioner was required, prior to the delivery of health care via telehealth, to obtain the patient’s verbal consent for its use. Physicians and physician groups soon complained that the new requirement meant that consent was needed before each telehealth session and that this requirement was onerous and burdensome on their ability to treat patients efficiently. In response to these complaints, the law was again amended to require the health care practitioner initiating the use of telehealth to simply inform the patient of its use and to obtain verbal or written consent (prior to the delivery of health care via telemedicine) “for the use of telehealth as an acceptable mode of delivery of health care services and public health.” Today, this initial consent is all that is required by law – that is, a new consent is not required before each telehealth session.

How did the California licensing board choose to clarify or explain this telehealth law in regulations? They passed regulations that appear to expand/amend or conflict with the law, which could render the regulation void and unenforceable. The regulation provides, in part, that upon initiation of telehealth services, the licensee must obtain the informed consent from the client consistent with Section 2290.5 of the Code. This statute, however, as described above, eliminated the requirement of informed consent almost five years ago! How can there be consistency with Section 2290.5 of the Business and Professions Code? Perhaps the regulatory board was not aware of the repeal of the informed consent requirement, or perhaps they did not recognize that there is a difference between a simple consent and informed consent.

Moreover, the regulation requires the licensee to inform the client of “the potential risks and limitations of receiving treatment via telehealth” even though that specific requirement was also repealed from the law. Not only does this regulatory provision seem to amend or expand the law, it conflicts with the law that it supposedly implements (there is no consistency between the regulation and the law). Additionally, the regulation curiously omits the other side of the informed consent equation – the potential benefits of receiving treatment via telehealth. Why would a regulation requiring informed consent omit the benefits side of the equation? Was it the result of intention or oversight? Finally, the telehealth law requires consent prior to the delivery of healthcare via telehealth, while the recently enacted regulation requires informed consent upon initiation of telehealth services. All of the above-described inconsistencies are troubling and problematic.

Regulations passed by a licensing board must define or clarify the law that they implement; they cannot conflict with the law and they cannot expand or contract the law. Changing or expanding the law requires legislation – it cannot lawfully be done by regulation. Why didn’t the board seek legislation if

they intended to change the law to again require informed consent after it was knowingly repealed from the law? Why didn't the board seek an exception to existing law for its licensees through the legislative process? Why didn't the board specify the key risks, consequences, and limitations it thinks warrant a mandatory disclosure, and why didn't they do so through legislation? Does the regulation change the law impermissibly? Did the licensing board exceed its authority?

Practitioners are left with questions and ambiguities. May they follow the requirements of the law (where only consent is required - not informed consent), since the regulation uses the term "consistent with the law" when addressing informed consent? Why should these practitioners have to specify the risks and limitations of treatment via telehealth as per the regulation (other than to avoid disciplinary action), when the regulation implements a law that intentionally repealed the requirement to specify risks and benefits (the hallmark of informed consent)? Physicians evaluate, treat, and monitor patients with serious illnesses via telemedicine - and they are not required by this law to disclose the potential risks or limitations of such treatment. They are expected to use their best professional judgment, to comply with applicable ethical standards, and to disclose such information that they determine is appropriate under the circumstances.

There are other areas of serious concern with the new regulations that are not addressed in this article. These other provisions appear to create arbitrary mandates that will result in confusion for practitioners and clients and will interfere with the efficient provision of telehealth services to clients of the mental health practitioners affected by these regulations. I leave a discussion of those concerns to another time.

What is the status of the law and any regulations related to telehealth and informed consent in your state? It is critical for the future development of the mental health professions that regulatory boards are informed and current when they implement telehealth public policy by creating new mandates. More importantly, they must do so only within their lawful authority. Licensing boards must go through the rigors and scrutiny of the legislative process when attempting to change the law; this is essential to assuring that government does not exceed or abuse its lawful authority or power.