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HEALTH LAW NEWS

SEPTEMBER 01, 2016

NEW WISCONSIN PAIN CLINIC CERTIFICATION REQUIREMENT ENACTED

The recently passed Wisconsin Act 265 (the "Act") establishes a new statutory requirement that all "pain clinics" obtain and maintain a special certification to be issued by the Wisconsin Department of Health Services ("DHS"), Division of Quality Assurance ("DQA"). Any organizations engaged in providing pain clinic services should carefully assess whether this requirement applies to them.

The Act defines a pain clinic as either: (i) a "privately owned facility where a majority of the health care providers, practicing within the scope of their licenses, devotes a majority of their practices to the treatment of pain syndromes through the practice of pain medicine or interventional pain medicine"; or (ii) a "privately owned facility that advertises or otherwise holds itself out as providing pain medicine or interventional pain medicine services and that has one or more employees or contractors who prescribe opioids or opiates, benzodiazepines, barbiturates, or carisoprodol as chronic therapy for pain syndromes."

Under the Act, a pain clinic may not operate unless it holds a certificate issued by DHS. Accordingly, providers operating pain clinics subject to the Act's requirements must apply for pain clinic certification by **September 22, 2016**.

The pain clinic certification standards could have significant operational implications for affected providers. Among other requirements, pain clinics in Wisconsin are now restricted from dispensing certain prescription drugs without a pharmacy license and may not accept cash payments from patients. A failure to comply with these pain clinic certification requirements could result in a revocation of the pain clinic's certification in addition to a civil forfeiture of up to $1,000 per day for each day of continued violation.

We further summarize below the main pain clinic certification requirements of the Act, with a special emphasis on how such requirements may affect hospitals and other integrated health systems.

CLINICS SUBJECT TO CERTIFICATION REQUIREMENTS

The Act exempts certain categories of health care providers from the pain clinic certification requirement. These exempted categories include: (i) medical, dental, nursing or physician assistant schools (or outpatient clinics associated with such schools); (ii) hospitals; (iii) hospices; and (iv) nursing homes. The Act's referenced definition of "hospital" includes not only the main hospital structure but also "related facilities such as outpatient facilities, nurses', interns' and residents' quarters, training facilities and central service facilities operated in connection with hospitals."

Since regulations have not yet been published clarifying these relationships, a careful analysis of exactly what components of an organization are subject to the pain clinic certification requirements should be undertaken. While the Act will clearly apply to most free-standing traditional pain clinics, pain clinics operated as part of an integrated health system or in connection with a hospital will need to conduct a fact-specific analysis to determine whether they must comply with the Act's certification requirements.

CERTIFICATION REQUIREMENTS

The Act states that a pain clinic currently operating in Wisconsin must submit an application to DHS by September 22, 2016,[1] have a medical director who is a physician that practices in Wisconsin and pay an application fee. A pain clinic certification is valid for three years and must be renewed. Under the Act, a legal entity that owns more than one pain clinic may apply for a single certificate for all pain clinics it owns. The legal entity assuming responsibility for the multiple pain clinics, however, shall submit the following with its application: (i) a listing of each pain clinic site; (ii) the number of days each week a pain clinic operates; and (iii) the health care providers who are working on each day of operation at each site.

In order to apply for certification as a pain clinic, an applicant must contact the DHS-DQA for application instructions and an application form. Interestingly, no copy of the application form is currently available to the public.

OPERATIONAL IMPLICATIONS

The Act states that a pain clinic may not accept cash payments and may only accept payments that are traceable to the individual seeking treatment. A pain clinic also may not directly dispense a monitored prescription drug[2] that is administered orally unless the pain clinic is also

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licensed as a pharmacy or the pain clinic is treating an individual reasonably related to a worker's compensation claim. As such, pain clinics subject to the Act should carefully review their dispensing practices and payment workflows/mechanisms, in addition to their licenses, to ensure that they are in compliance with the Act.

PRACTICAL TAKEAWAYS

The Act grants DHS the rule-making authority to "promulgate rules to govern the operation of pain clinics as the department finds necessary to provide safety to the public" or as necessary to implement the Act. As of August 31, 2016, however, we are not aware of any pending or final rules by DHS pertaining to pain clinics. Until DHS decides to promulgate rules to clarify the Act's implementation scope, the statutory requirements set out in the Act are the sole guidance concerning the operation and licensure of pain clinics.

Going forward, health care entities, particularly those that do not clearly fall into the exceptions to the pain clinic certification requirements, should carefully review the Act and ensure that they are in compliance with its requirements. The current requirements set forth in the Act are rather broad, and given the potential risks, any potential pain clinic applicant should conduct a thorough fact-specific analysis of the applicability and requirements of the Act. Finally, any potentially affected health care entities should stay alert for potential DHS rule-making on this topic.

If you have questions regarding Wisconsin's new pain clinic certification requirements, please contact:

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[1] According to the Act, a pain clinic currently in operation may continue to operate so long as the pain clinic submits an application for certification within 30 days after DHS publishes the application process on its internet site. DHS published the application process on August 23, 2016.

[2] "Monitored prescription drug" means a substance specifically identified under Wisconsin law, namely under Wis. Stat. §§ 961.16, 961.18, 961.20, or 961.22, or a drug identified by the controlled substances board by rule as having a substantial potential for abuse. Wis. Stat. § 961.385.

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