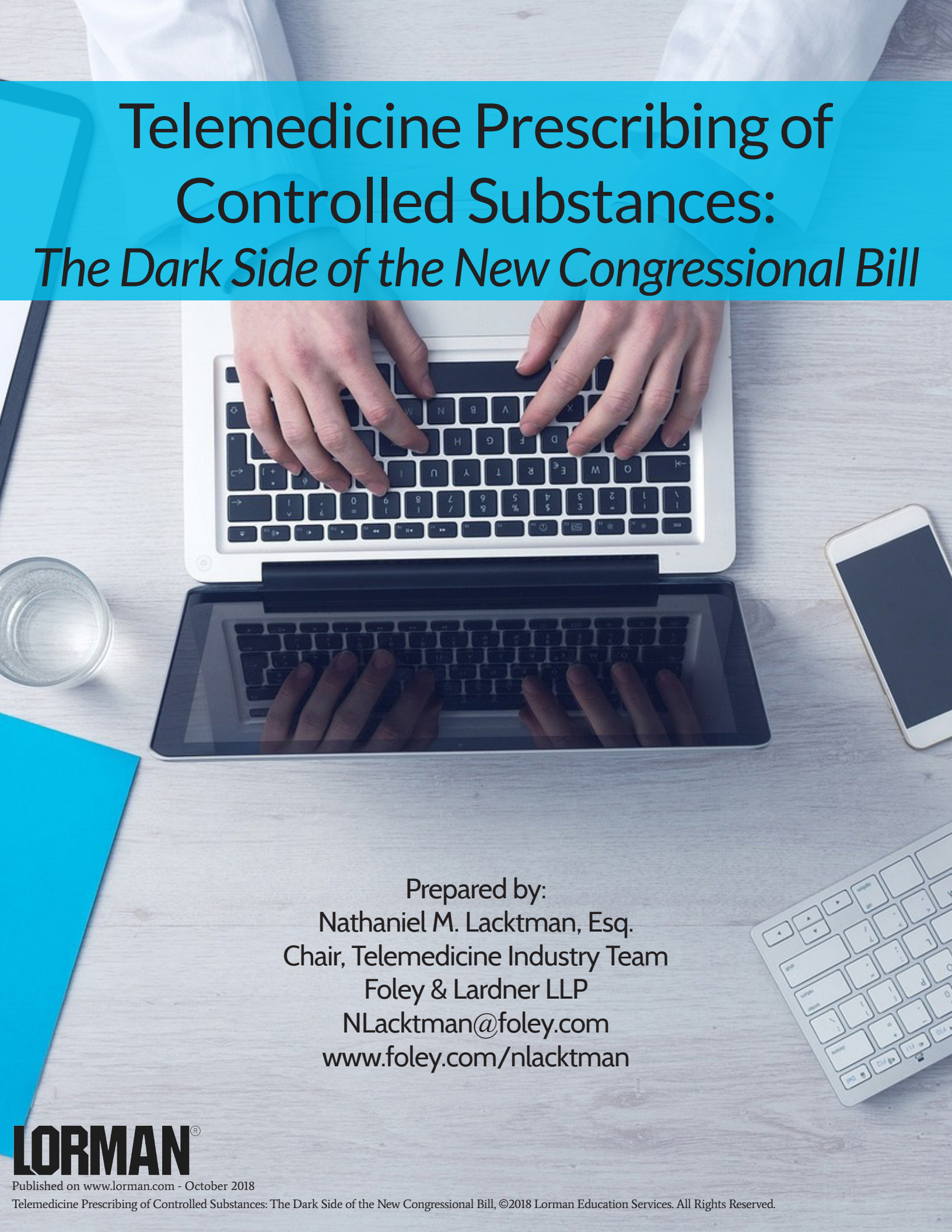
Telemedicine Prescribing of Controlled Substances:

The Dark Side of the New Congressional Bill



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Telemedicine Prescribing of Controlled Substances: The Dark Side of the New Congressional Bill

Written by Nathaniel M. Lacktman – 4/29/18

Congress has taken another step forward to require the federal Drug Enforcement Administration (DEA) to activate a special registration allowing physicians and nurse practitioners to prescribe controlled substances via telemedicine without an in-person exam.

The House Energy and Commerce Health subcommittee approved the Special Registration for Telemedicine Clarification Act of 2018, part of a larger package of legislation designed to give healthcare providers more tools to combat the opioid crisis and expand access to medical care. POLITICO's Morning eHealth reporter Darius Tahir first reported on the new legislation.

What Does the New Bill Accomplish?

The Special Registration for Telemedicine Clarification Act requires the Attorney General, with the Secretary of Health and Human Services, to promulgate interim final regulations activating the Ryan Haight Act special registration for telemedicine. While the current Ryan Haight Act already requires the DEA to *create* the special registration, there is no deadline for the DEA to *activate* the registration. This new bill is intended to "light a fire" and require the DEA to promulgate interim final regulations no later than 90 days after the bill is enacted.

The special registration is one of seven exceptions to the Ryan Haight Act's in-person exam requirement. Practitioners who apply for and obtain the special registration are allowed to use telemedicine to prescribe controlled substances without an in-person exam under federal law. The complete language of the bill states:

> Section 311(h)(2) of the Controlled Substances Act 8 (21 U.S.C. 831(h)(2)) is amended by striking ''The Attorney General shall, with the concurrence of the Secretary, promulgate regulations'' and inserting ''Not later than 90 days after the date of enactment of the Special Registration for Telemedicine Clarification Act of 2018, the Attorney General shall, with the concurrence of the Secretary, promulgate interim final regulations''.

What's the Reason for this New Bill?

The need for DEA to activate the special registration is evident to those in the telemedicine industry who use controlled substances in connection with their patient care.. Activation of the special registration has the potential to expand the ability to prescribe controlled substances via telemedicine, opening opportunities for direct-to-patient models, particularly for specialties such as treatment for substance use disorders , psychiatry, and endocrinology (all of which utilize controlled substances in connection with medication-assisted therapy). Unfortunately, despite the Ryan Haight Act being passed nearly ten years ago, the DEA has never activated or made available this special registration to allow providers to prescribe controlled substances via telemedicine without the need for an in-person examination and without the need for the patient to be physically present in a hospital or other DEA-registered clinic.

For years, DEA has been working on a proposed regulation activating the special registration process, but thus far has not published anything. While DEA's unified agenda has announced expected publication dates in the past, those dates have repeatedly been extended and deadlines missed. Hence, the new Congressional bill.

What's the Problem with the Proposed Bill?

At first blush, the bill appears to accomplish what telemedicine providers have been requesting: to compel the DEA to issue regulations within a federally-imposed deadline. However, industry advocates should be very cautious about this bill because it requires the DEA to issue "interim final regulations." Typically, the process of federal regulations starts with a proposed rule, published and shared with the public. The public then usually has a period of time, typically 90 days, to read the proposed rule and submit comments to the federal agency. The agency then must read, consider, and publicly respond to each and every comment. The comments and responses are then published in a final regulation available for the public to review. This procedure is an iterative process allowing the public (including those in the telemedicine industry) to comment on and suggest changes to the regulation before it is finalized.

In contrast, an interim final regulation would have the DEA simply publish the rule and effective date, often without officially considering or responding to public comments. The risk, as it relates to the Ryan Haight Act, is that the DEA's regulations might not be aligned with the best interests of patients and telemedicine prescribers, and there would be no opportunity for the telemedicine industry to share their comments and suggestions for improvement with the DEA. ***Remember: this is exactly what happened nine years ago when the Ryan Haight Act was first signed into law.*** The DEA issued an interim final rule enacting the Ryan

Haight Act provisions, and the rule was effective a mere nine days after it was published, leaving no time for public comment.

Is There a Better Approach?

While the Special Registration for Telemedicine Clarification Act is a good step forward, an even better approach might be for Congress to set deadlines for the DEA to first issue proposed regulations within 90 days of the bill's effective date. Congress could also require the DEA to issue final regulations within 180 days of when the proposed rule is issued, or within a reasonable period following the deadline for submission of public comments in response to the proposed rule. Consider, for example, the following alternative language:

> Section 311(h)(2) of the Controlled Substances Act 8 (21 U.S.C. 831(h)(2)) is amended by striking ''The Attorney General shall, with the concurrence of the Secretary, promulgate regulations'' and inserting ''Not later than 90 days after the date of enactment of the Special Registration for Telemedicine Clarification Act of 2018, the Attorney General shall, with the concurrence of the Secretary, promulgate proposed regulations and allow for a public comment period of 60 days. Not later than 180 days after the date of the proposed regulations, the Attorney General shall, with the concurrence of the Secretary, promulgate final regulations to be effective not later than 30 days after publication.''.

Under this alternate approach, the healthcare providers and prescribers and patients who care most about this issue would have an opportunity to review a proposed rule and submit comments for the DEA to consider and incorporate into a final rule. Directing the DEA to issue interim final regulations, while expeditious, strips the public from the important need

to review and comment on the DEA's approach to the special registration process.

We will continue to monitor progress of both bills and other developments on the Ryan Haight Act, so please check back for updates.

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