



## BioDelivery Sciences Cites Impressive Number of Physicians Granted Waiver to Increase Patient Limit for Opioid Dependence Treatment Following Recent HHS Rule

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SAMHSA Reports 1,665 Clinicians Granted Waivers at the Increased Limit as of This Week

RALEIGH, N.C., Sept. 30, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) reported that according to the Substance Abuse and Mental Health Services Administration (SAMHSA), 1,665 clinicians have applied for and were granted waivers to prescribe buprenorphine for the treatment of opioid dependence at the increased limit of 275 from the previous 100.

The limit on the number of patients an eligible physician can treat with buprenorphine went from 100 to 275 this past August, based on a rule by the Department of Health and Human Services (HHS) as part of an initiative to increase access to medication-assisted treatment. HHS had estimated that between 500 and 1,800 practitioners would request approval to treat up to 275 patients within the first year, resulting in an estimated range of 10,000 to 90,000 additional patients.

"The need for increased access to buprenorphine treatment has been demonstrated by the large number of healthcare providers that promptly filed to expand the number of patients they could treat. This and other efforts increasing access to care are important steps forward in helping to address the opioid dependence epidemic in the U.S.," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BioDelivery Sciences. "After less than two months since the rule went into effect, the number of clinicians applying for and granted the waiver is already in the upper range of expectations from HHS for the entire first year."

### ***About BioDelivery Sciences International***

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA<sup>®</sup>) technology and other drug delivery technologies to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs.

BDSI's development strategy focuses on utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's particular area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence. BDSI's headquarters is located in Raleigh, North Carolina.

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