September 11, 2018

Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DRW
8701 Morrissette Avenue
Springfield, VA 22152

RE: Proposed Production Quotas for Controlled Substances (Docket DEA-488P]

Dear Mr. Dhillon:

Enclara Pharmacia appreciates the opportunity to submit the comments below on the Drug Enforcement Administration's (DEA's) proposed rule on Controlled Substance Quotas (83 Fed. Reg. 42164).

Enclara Pharmacia is a national, full-service supplier of medications and clinical management support to hospices. The company services over 500 customers and 85,000 hospice patients in 48 states through its mail service pharmacies and clinical call center.

As a national provider with pharmacies dispensing controlled substances to patients throughout the United States, Enclara Pharmacia recognizes the challenges posed by the opioid epidemic. Our pharmacists work with hospice clinicians and family members every day to ensure that patients receive the medications they need. We do so while also providing clinical support tools, education and best practices to help prevent potential misuse or diversion.

Enclara Pharmacia recently inaugurated an Opioid Stewardship Program to provide our customers with policies and procedures, risk assessments and training for clinicians, as well as education and other resources for patients and families. We also formed an Opioid Task Force which currently includes representatives from 145 hospices to share best practices and drive strategy for the Opioid Stewardship Program.

Enclara Pharmacia understands that excess quantities of opioids accessible to the public augments the risk of diversion and abuse. We recognize that the intention of DEA production quotas is to avoid large surpluses of controlled substances, while also ensuring sufficient quantities to meet legitimate patient needs. However, we are concerned that production quotas could have unintended negative consequences for hospice and palliative care patients.

Enclara Pharmacia is concerned the reduced 2019 production quotas for controlled substances, especially morphine, hydromorphone and fentanyl could negatively impact hospice patient care as they are used most commonly for patients with escalating pain. The health care industry has been battling shortages of parenteral opioids since the first quarter of 2018. Oral, solid opioid dosage forms are often the sought-after alternatives but are only useful for patients with the ability to swallow. As you are well aware, health care providers are also currently experiencing a shortage of oral liquid morphine, which is particularly critical to manage pain and shortness of breath commonly experienced by patients at the end-of-life, especially those who lose the ability to swallow tablets or pills. These shortages are not likely to be resolved soon, so further cutting the production quota for morphine, and other opioids, may only aggravate the situation in an

industry that is already struggling to manage its sickest patients. Without a reliable supply of liquid morphine, Enclara Pharmacia is concerned that hospice patients may be placed at risk of having unmanaged symptoms during their final days and hours.

Enclara Pharmacia is also concerned that the proposed cuts in 2019 production quotas are not supported by evidence that such cuts will reduce the diversion or abuse of opioids. The Federal Register notice and accompanying press statements do not provide any references or literature demonstrating that reducing production quotas positively impacts diversion or abuse. Enclara Pharmacia believes that continuing to cut production quotas should be supported by sound evidence and a cost-benefit analysis – balancing potential risks and harms against the legitimate needs of patients. We believe such a process for determining production quotas is warranted, given the vulnerability of patients at the end of life who depend on opioids for palliative care.

Thank you for the opportunity to share our feedback on the proposed production quotas. Enclara Pharmacia would welcome the opportunity to discuss these issues further and share our unique perspective on this matter.

Please feel free to contact me if you have any further questions or comments. I can be reached at jloxterman@enclarapharmacia.com or 215.282.1737.

Sincerely,

John R. Loxterman
SVP, Chief Ethics and Compliance Officer