

The American Academy of Pain Medicine is pleased to comment on the question of facilitating access to naloxone for the treatment of opioid overdose.

Naloxone saves lives if administered to a person experiencing a serious opioid overdose. It has no serious adverse effects if given in error to a person who has a different reason for diminished responsiveness. While it may cause uncomfortable withdrawal symptoms in some, these are not dangerous and are transient. Very rarely, it may provoke cardiac symptoms in patients treated with opioids.

Thus this is an intervention with no significant down side other than cost.

In several states first responders now carry naloxone and have prevented deaths by treating overdose victims. Since the duration of the opioid overdose may well exceed that of naloxone reversal, it is critical that all users be educated to obtain emergency medical attention following administration, even if the patient appears asymptomatic.

In some states physicians can prescribe the kit without establishing a patient-physician relationship. The kits are to be used by family members or concerned individuals in case of emergency; i.e., a parent who is concerned that a heroin-addicted child might overdose could lawfully obtain and administer naloxone to the child.

The most useful regulatory interventions, in the opinion of the Academy, would be those that reduce existing barriers to the widespread availability and use of naloxone.

- 1) Many who might use the drug do not have a physician to prescribe it, may not be able to afford an office visit, transportation, parking, etc.

Pharmacists should be empowered to dispense naloxone overdose kits without a prescription from a physician and to provide education in their use. In several states, this recommendation has been implemented.

- 2) Provision of an injection requires a degree of skill and is aversive to many. The further development and availability of non-injectable (e.g. nasal) alternatives should be encouraged.
- 3) Those likely to use the drug should be made aware of the safety and usefulness of naloxone treatment of overdose via a public education campaign.
- 4) Physicians should be encouraged to consider co-prescribing naloxone when prescribing opioids in high risk situations, such as high dose therapy, combined therapy with benzodiazepines/sedatives, opioid therapy in obese patients, especially those who have obstructive sleep apnea.

The Academy is supportive of the efforts of the FDA to maximize the availability of this life-saving therapy.