

NASPER Funding Approved by Congress

On March 11, President Obama signed into law as part of the Omnibus package an appropriation of \$2 million in funding for the National All Schedules Prescription Electronic Reporting Act (NASPER). NASPER was enacted on August 11, 2005, and directs the Secretary of Health and Human Services (HHS) to provide grants to states to implement or improve their prescription monitoring program (PDMP's).

Unlike the Harold Rogers grant program, administered by the Department of Justice, that allowed states to establish their own requirements with regard to schedules monitored, information sharing, and accessibility/availability to the program data, states will be required to collect data for Schedules II-IV in order to be eligible for NASPER funding. Additionally, NASPER requires that states submit plans for interoperability (the capacity to share information and prescription data among states.)

Although NASPER was authorized in 2005, Congress until now had failed to appropriate funds to HHS. Appropriated funds were necessary to begin to implement NASPER.

NASPER's provision include:

- NASPER fosters interstate communication by providing grants to set up or improve state systems that meet basic standards of information collection and privacy protections that will make it easier for states to share information.
- The Secretary of Health and Human Services (HHS) is charged with developing minimum standards to safeguard personal information. The Secretary will only be able to approve an application for a NASPER grant if a state meets these requirements, which must include use of encryption technology, limiting access to approved personnel, and defined penalties for unauthorized use or disclosure of information contained in the database. Furthermore, states are also welcome to enact privacy protections above and beyond federal requirements.
- To be eligible for a NASPER grant, States must have enacted laws or regulations to permit implementation of a PMP and the imposition of appropriate penalties for the unauthorized use and disclosure of PMP information.
- Importantly, this Fiscal Year 2009 appropriation must be

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obligated by September 30, and must follow a Federal Register notice to solicit comments on minimum standards. To meet these deadlines, it is conceivable that States would need to be in a position to submit grant applications no later than early to mid-July."

NASCSCA will be closely monitoring this recent development and will be sharing any news in this regard with our members and others interested in this new initiative.

For a copy of the NASPER bill visit our website at www.NASCSCA.org under Prescription Monitoring Programs.

FDA Acts to Halt Marketing of Certain Unapproved Narcotic Drugs

On March 31 The U.S. Food and Drug Administration warned nine companies to stop manufacturing 14 unapproved narcotic drugs that are marketed in several dosage forms and are widely used to treat pain.

The FDA's warning letters notified the companies they may be subject to enforcement action if they do not stop manufacturing and distributing prescription unapproved products that include high concentrate morphine sulfate oral solutions and immediate release tablets containing morphine sulfate, hydromorphone or oxycodone. This action does not include oxycodone capsules.

<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01983.html>

<http://www.fda.gov/cder/drug/unapproved%5Fdrugs/narcoticsQA.htm>