The Drug Enforcement Administration’s (DEA’s) proposal to allow the pharmacy industry to switch to electronic ordering for class I and II controlled substances might be a boon in many respects—but the plan poses some potential pitfalls too.

Painkillers, sedatives, and the other narcotics that are designated class I and II drugs are a big business, of course, legally and otherwise. The DEA’s efforts over the past few years to crack down on the diversion of controlled-release oxycodone HCl (OxyContin®, Purdue Frederick), the opiate painkiller, have grabbed headlines. In some instances, the DEA has gone a little overboard because of misinformation.

John Rector, senior vice president at the National Community Pharmacists Association, says that the DEA recently raided a suburban Virginia pharmacy, with shotguns drawn, after misinterpreting an electronic order for “oxycon” as being for OxyContin®. Actually, the order was for oxygen containers, but that shows how nervous the DEA is.

Currently, pharmacies that order class I and II drugs and suppliers that provide them must fill out the DEA’s Form 222. Drugs can be ordered electronically, but forms for these orders must be sent separately. Some pharmacies use Express Mail, but this method can become expensive. Because many suppliers either send the form back to the purchaser on the delivery truck or mail it, pharmacies don’t receive the drugs for two or three days anyway; they must wait even longer if the distributor doesn’t have the drugs and assigns the order to a second distributor. So, off goes Form 222 again. Its journey now becomes even longer. With approximately five million of these forms filed in 2001, one can imagine how clogged the distribution pipeline can become.

Of course, creating an electronic version of Form 222 will not be easy because of the need to protect the security of the transaction. Given the ease with which computers can be manipulated by hackers, there must be a way to make sure that purchasers are who they say they are and that the DEA clears them to buy controlled substances.

To accomplish this safely, the DEA has selected “public key infrastructure (PKI) technology,” which provides sophisticated data encryption and decryption methods to preserve the security and integrity of electronically transmitted data. Each transmission will contain a digital certificate that validates the user and assures authenticity. Retailers use this type of system to verify the validity of credit cards presented by customers. Because each digital signature is linked to an individual DEA registration, separate digital signatures would be required for pharmacies with multiple locations.

This method, however, can complicate compliance for chain drugstores. Mary Ann Wagner, vice president of regulatory affairs for the National Association of Chain Drug Stores, says that each of a chain’s pharmacies would have to have one pharmacist who “holds” the digital certificate and signature for that store. To the extent that pharmacists come and go, that can create problems with ordering for the store. Ms. Wagner thinks that the large chains might centralize their ordering of class I and II drugs in corporate headquarters (community drugstores usually handle only class II), so only one digital certificate is needed. She adds, however, that small chains and single pharmacies might even stick with the current paper Form 222, which they can continue to use because the electronic 222 will be voluntary.

The DEA says the idea for an electronic Form 222 originated with the industry. Ms. Wagner confirms that the electronic system will have many benefits; faster receipt of products and smaller inventory are the most prominent advantages. Tom Clark, director of policy and advocacy for the American Society of Consultant Pharmacists, also praises the DEA for offering digital signatures for Form 222.

The DEA thinks that its initiative will save the pharmacy industry $1.6 billion over 10 years. That may be an overstatement, but in the current economy, of course, any cost savings are welcome.