After a few years of revving up its regulatory engine, the Food and Drug Administration (FDA) is ready to move forward with a proposal for bar coding pharmaceuticals. The idea is to use bar coding to cut down on the kinds of medication errors that were first highlighted in the National Academy of Science’s November 1999 report, “To Err is Human.”

Two years later, confirmatory reports and papers are still being written. In the October 1, 2001 issue of the *American Journal of Health-System Pharmacy*, officials from the FDA’s Center for Drug Evaluation and Research (CDER) published statistics based on 1993 to 1998 reports to the FDA’s Adverse Event Reporting System. Of 5,300 reports of medication errors, 68.2% resulted in serious patient outcomes, and 9.8% were fatal. Those numbers were based on reports from hospitals, ambulatory care facilities, and homes. In terms of the deaths, the most frequent (41%) causes were administering the wrong dose (41%) and the wrong drug (16%).

Bar coding has been talked about for use primarily in institutional settings; hospitals and nursing homes are the top priority venues. However, the National Coordinating Council for Medication Error Reporting and Prevention “believes these recommendations may have broader application to other settings.” The Council has a broad membership, reaching into nearly every pharmaceutical trade and professional association of consequence. The FDA is also a member.

The Council recommended that the FDA and U.S. Pharmacopoeia supervise the development of uniform bar code standards, and suggested the elements that should comprise any bar code. It is these recommendations that will form the basis of the proposed rule the FDA is expected to issue this year.

Many prescription and over-the-counter drugs already have bar codes. But those bar codes only contain the “National Drug Code” number. The National Coordinating Council recommendations call for two other pieces of information to be included in the bar code: the lot number and the expiration date.

The FDA’s intention to act was announced by Assistant U.S. Health Secretary Bobby Jindal in early December to the American Society of Health-Systems Pharmacists (ASHP), which has long pushed for bar codes. Jindal gave no details, however. Tom McGinnis, Director of Pharmacy Affairs for the FDA, said in an interview that the agency is at the beginning of assembling a proposal. Initially, the FDA had intended to disseminate a proposed rule by April. That date has since been pushed back; McGinnis then expected a proposal to come out some time in 2002. Whenever a proposal is published, public comment will be sought and analyzed before a final rule, with an effective date, emerges.

But what kind of proposal will it be? McGinnis said that the key driving factor in whatever the FDA proposes will be the costs that manufacturers have to incur. He pointed out that many prescription and over-the-counter drugs already have bar codes. But those bar codes only contain the “National Drug Code” number. The National Coordinating Council recommendations call for two other pieces of information to be included in the bar code: the lot number and the expiration date.

Another important issue is which containers and packages should require bar codes. The Council endorsed bar codes on all immediate unit-of-use packaging, which can include single-unit, single dose, unit-dose, multiple unit, and multiple dose containers.

Drug manufacturers are not apt to embrace any FDA proposal fully and unconditionally. After Jindal made his speech to ASHP, Jeff Trewhitt, a spokesman for Pharmaceutical Researchers and Manufacturers of America (PhRMA) said, “This could potentially help cut down on errors but the devil is in the details and we need to see the details. This is going to be technically challenging, potentially time-consuming and potentially very expensive.”

The ASHP sees bar coding as very positive from the cost–benefit perspective. Gary Stein, ASHP’s Director of Federal Regulatory Affairs, said that depending on how much information is required in the bar code, the changes could cost drug manufacturers between $500 million and $1.4 billion over 10 years. But that figure is dwarfed by the annual costs associated with errors in administering prescription drugs.