The key unanswered question about the proposed rule by the Food and Drug Administration (FDA), which would require bar codes to be placed on drugs that are sold to hospitals, has nothing to do with the pharmaceutical industry. To paraphrase Bill Clinton: “It’s the hospitals, stupid!” Pharmaceutical manufacturers can add bar codes to their products to a fare-thee-well, but if the hospitals do not purchase the expensive scanners needed to read those bar codes, the whole effort to reduce medication errors will be for naught.

In the FDA’s proposal, issued in March 2003 after years of contemplation, the agency offered a little something for everyone. Despite statements made in the press releases issued by the trade groups affected, however, not everyone was satisfied.

For example, the FDA did the Pharmaceutical Research and Manufacturers of America (PhRMA) members a favor by not requiring the bar codes to contain the drug’s lot and expiration numbers, as the American Society of Health-System Pharmacists (ASHP) and others had wanted. Only the National Drug Code number will be encapsulated in the bar code. On the other hand, PhRMA members were hoping that they would not have to place bar codes on unit-of-use packages, such as the foil-backed, two-capsule servings that are torn off from a blister pack. Adding bar codes to packages this small is possible, but it is also expensive. Drug companies will have to put a bar code not only on the individual dose but also on the blister sheet.

Bar codes will also be needed on over-the-counter unit-of-use packages that are distributed in hospitals. This requirement doesn’t exactly make the Consumer Healthcare Products Association (CHPA) want to kick up its heels and dance. But the FDA threw the CHPA a bone of sorts by not requiring bar codes on over-the-counter drugs sold at retail stores.

Once the final rule is published—which won’t be until fall 2003 at the earliest—drug manufacturers will have three years to comply. Hospitals, however, will not need to comply; either they will buy bar code readers, or they won’t.

Kasey Thompson, PharmD, director of the Center on Patient Safety for the ASHP, thinks that hospitals will buy the scanners despite their probable heavy cost. He chalks that optimism up to a cost/benefit analysis. “Forty percent of the mistakes hospitals make have to do with medication errors,” he says.

The issue of equipment cost, however, is up for grabs, as the FDA acknowledges. To begin with, the FDA wants to require linear bar codes without specifying a particular type. The Uniform Code Council (UCC) has established the American standard, accepted by the majority. The UCC specifies a number of “symbologies,” or different types of codes. The FDA acknowledges that the Health Industry Business Communication Council has its own, unique linear symbologies. The FDA is confident that when the bar code rule becomes final, linear scanners will be able to distinguish the difference between those symbologies—well, maybe they will and maybe they won’t.

Even if all linear scanners could distinguish between all linear bar codes, there would be another potential problem. Pharmaceutical packagers can reduce the size of a linear bar code by using a “reduced-space symbology” (RSS) format, which allows miniaturized bar codes to be applied to packages as small as the cap of a pen. Abbott Laboratories used the RSS format to place bar codes on 1,000 products in its line of hospital injectable and intravenous solutions.

Even RSS bar codes, however, cannot fit on the back of a unit-of-use, foil-backed antihistamine, for example. The bar codes must be put in a two-dimensional, data-matrix format. Linear readers, which use lasers, cannot read data-matrix bar codes; only optical scanners can do that because they use cameras. Optical scanners are more expensive than linear scanners.

According to 1999 data from the ASHP, only 1% of U.S. hospitals use scanners at the bedside, and these are linear scanners. Given current hospital economics, it is going to be difficult enough for hospitals to go on a shopping spree for linear readers. If they have to buy optical readers in addition, or instead, their checkbooks may never leave their pockets.