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March 25, 2003

Dockets Management Branch (HFA-305)
Federal Drug Administration
5630 Fishers Lane, Room 1061
Rockland, MD 20852

Re: FDA Proposal for Medication Bar Coding and Drug Event Reporting

I have reviewed the two proposed FDA rules to help reduce medication mistakes and identify potential drug errors. Following are several comments I would like to bring forward.

1. I agree with the proposal to require bar codes on all prescription drugs, which will include the drug name, dosage form, and strength. **However, the requirement should be expanded to include the medication lot number and expiration date, which is critical to protect patients from recalled or expired medications.**

2. Reporting within 15 days actual and potential (near miss) errors **would impose an additional burden on already overloaded hospital staff. This would present a large problem that would require additional staff or staff hours, and financial resources to implement.**

3. The proposed safety report requiring the patient name violates patient rights of privacy and is in direct conflict with the federal Health Insurance Portability and Accountability Act of 1996. **The patient name would not provide any beneficial information in statistical analysis of the data.**

As a patient safety advocate, I applaud the FDA's efforts to improve patient safety through these new measures. However, please give careful consideration to a patient's right to privacy and potentially costly implementation of the proposed requirements. I represent a small, rural hospital that will experience a significant financial impact with the implementation of these rules.

Sincerely,

Dona J. Martinson

Dona J. Martinson
Chief Operating Officer

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