August 20, 2002

Mary C. Gross
Policy Analyst
Food and Drug Administration
5600 Fishers Lane
Rm. 15B32
Rockville, MD 20857

Dear Ms. Gross:

On behalf of the more than 1,600 leading not-for-profit hospitals and health systems allied in Premier, I thank you for permitting our vice president for contracting, Bert Patterson, to testify at the July 26 public meeting on bar coding. We were pleased at the informative dialogue that took place, and encouraged by the strong interest expressed, by both agency officials and health industry stakeholders, in the promulgation of a rule.

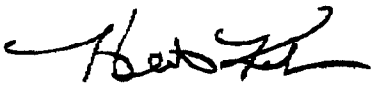
We believe the forum demonstrated overwhelming support for the FDA's assumption of a critical role in the formulation of a bar code standard that would increase patient safety, reduce supply chain costs, and enhance clinicians' ability to research quality-of-care improvements. Premier has long regarded bar code adoption a critical component of our larger, broad-based strategy to assist our hospitals achieve the highest quartile in quality and the lowest quartile in costs.

To reiterate, Premier strongly supports efforts by the FDA to promulgate a rule to require the bar-code labeling of all hospital-administered drug, biologicals, and appropriate medical devices at every package level, especially that of the unit-dose. With respect to pharmaceuticals and biologicals, we support the recommendations issued by the National Council for Coordinating Medical Error Reporting and Prevention (NCC-MERP). We are cognizant, however, that a phased-in approach for achieving compliance with such a standard may represent a better strategy for ultimate success. Therefore, we believe the regulation issued in November ought to require the NDC code, while stipulating a reasonable timeframe in which the applicable bar code labels would contain the NCC-MERP recommended data.

With respect to the applicability of a bar code regulation to appropriate medical devices, we would point to the quality and quantity of testimony provided at the July 26 meeting stipulating that such inclusion is warranted. Dr. David Feigal, director of FDA's Center for Devices and Radiological Health, seemed to indicate that the bar-code labeling of devices could increase the percentage of re-called medical devices that are actually returned. Daniel Ashby with Johns Hopkins Hospital agreed, calling the coding of devices a valuable tool for ensuring that clinicians "get the message" with respect to device recalls. He pointed to the recent bronchoscope recall as a case-in-point.

Finally, Premier remains dedicated to working with the FDA and all interested parties, including the Advanced Medical Technology Association (AdvaMed), to devise an expeditious implementation strategy for this significant patient care opportunity. I thank you, again, for your leadership in this critical area, and look forward to working together to improve patient safety and quality of care.

Sincerely,



Herb Kuhn
Corporate Vice President
Premier Advocacy

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Review Management
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Comments: Please see new comment on barcoding human drugs + biologics
Thanks

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