make its initial and final determinations on the selection of drugs and the setting of MAC levels.

All of this, of course, impacts upon interested persons or organizations wishing to comment on a proposed MAC. In the absence of a specification of issues or standards, they cannot know what issues to address or what types of arguments to advance. Particularly distressing is the absence of any standards upon which the Board might base findings on the issues of quality and bioavailability.

In Part II-C above, we suggested specific criteria which might serve as a partial check list on the quality assurance and bioavailability issues. While we do not believe that adoption of such criteria would provide complete assurance on these issues, it would result in a far more reasonable program.

The proposed regulation also lacks standards to guide pricing determinations. The only guideline contained in the regulation for determining the appropriate MAC level is Section 19.5(c)'s reference to "the lowest unit price at which the drug is widely and consistently available to providers throughout the nation". No standards are suggested by which the Board could determine when a drug should be deemed to be "widely and consistently available". The regulation obviously does not contemplate that such a finding may be made only when the drug can be purchased at a particular price by pharmacists anywhere in the nation, for Section 19.5(c) recognizes the possibility of regional "loopholes", i.e., the establishment of separate MAC determinations for specific localities.

Hence a confusing vagueness permeates the regulation. What really does "widely and consistently available" mean? Moreover, how is the Board to know whether "lowest unit price" is to be determined on the