cost formulation under 42 U.S.C. § 1395u(b)(3), he must not do so unless he decides that the differing versions of that drug "do not vary significantly in quality from one supplier to another". And, of course, such a judgment must rest upon a reasoned evaluation of the evidence as to the possible existence of variations in quality.43/

Findings on the issues of quality assurance and therapeutic equivalence are therefore necessary to insure that the adoption of a MAC does not frustrate the achievement of policy objectives embodied in the federal health programs established by Congress. By the same token, an explanation of the Board's findings on these critical issues is essential if a reviewing court is to exercise effectively its responsibility "to assure that the agency has given reasoned consideration to all the material facts and issues."44/ A finding of quality assurance and therapeutic equivalence must precede the adoption of a MAC so that a reviewing court can determine whether the Board's action impermissibly prejudices the quality of medical care available to Medicare-Medicaid beneficiaries.

2. Absence of Standards

Another basic deficiency is the failure of the proposed regulations to specify standards to guide the Board and Advisory Committee in reaching their determinations. Section 19.5(d) of the MAC regulation, for example, does not tell the Committee what factors or standards it should consider in rendering its advice and in making its recommendations to the Board. Likewise, Board members and administrative law judges before whom an informal hearing may be conducted are not informed by Section 19.5(f) or (g) of the types of issues which they should consider at the hearing. Nor, except in the most general fashion, would the Board be provided with standards or guidelines against which to