therapy. Extensive comments are currently being reviewed. In similar fashion, the Social and Rehabilitation Service has under development proposed regulations prohibiting the use of grant funds under the medicaid and vocational rehabilitation programs for the payment of drugs classified as "ineffective" or "possible effective." A latent problem is assuring effective administration of this policy on a patient-by-patient and claim-by-claim basis.

The Social Security Administration instructed its intermediaries in April 1970 to assure reasonableness of drug cost reimbursements by a comparison of prices paid by each provider with prices at which the drugs are available in the provider's areas for a random sampling of charges.

Title XIX of the Social Security Act states that the State plan for medical assistance must assure that payments for drugs are not in excess of reasonable charges consistent with efficiency, economy, and quality of care. Some 20 States have developed formularies which list eligible drugs and the maximum amounts that will be paid for such drugs. The regulations on reasonable charges for drugs require a State plan under title XIX to include a description of the reasonable charge policy and the methods to be used in the State's medical assistance plan. They require the State agency to take whatever measures are necessary to assure the appropriate audits of records. In addition to the State audits, Department audit teams and General Accounting Office audit teams have reviewed State programs to determine the reasonableness of reimbursements.

Senator NELSON. When were these formularies developed? Do you know during what period of time these formularies were developed by the 20 States?

Mr. RICHTER. Since the beginning, perhaps in January 1966. I don't know when most of them were put into effect.

Senator NELSON. Does the Department have copies of the formularies that these States have designed?

Mr. RICHTER. I believe we can get them, I think we have some of them in our files.

Senator NELSON. Has the Department made any evaluation of the quality of these formularies?

Mr. RICHTER. May I ask our drug man to comment on that.

Mr. Rose, did you hear the question the Senator asked?

Mr. ROSE. What is the question, please.

Senator NELSON. My question was: Has the Department made any evaluation of the quality of the formularies that have been developed by the 20 States that have adopted formularies since 1966?

Mr. ROSE. The States have various methods of assuring quality for the drugs under formularies. One State in particular has requested all the manufacturers to submit an application before the drugs can be included in their formulary. That State is Pennsylvania. They have to submit their compliance with the FDA's manufacturing procedures, et cetera. Since drugs is an optional service, formularies and generic drugs are also optional, but where either is employed, they must be under the supervision of professional personnel, in assuring the quality and safety of drugs.

At the Federal level, of course, it is the responsibility of the FDA to assure that drugs are safe and effective; and each State has its own