

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 12377

conduct controlled trials of generically similar compounds in order to test the patient's tolerance and response to them. Such a procedure would not only be impractical but ethically questionable as well.

In practical terms, then, the certification exception, allegedly designed to preserve appropriate professional discretion, would do nothing of the sort. Although it is not clear what would happen if a physician prescribes a product priced above the MAC level without making the required certification, the MAC program would almost surely have the effect of pressuring him to conform to the federal guidelines.

In this connection, we note that the proposed complementary Medicare regulation³⁴ departs from both the basic MAC regulation and the implementing Medicaid regulation³⁵ by requiring a written "medical justification" for the certification of an exception. Would additional or different certifications be required depending upon the program under which reimbursement is being made? Such a practice would be intolerable, if only because it would be administratively unworkable.

Pharmacists are treated even more severely under the proposed regulation, for their professional prerogatives are not recognized at all. If the pharmacist received a generic prescription for a drug included in the MAC listing, he would have no choice but to dispense a product falling at or below the MAC price ceiling -- unless, of course, he is willing to accept less than full reimbursement for the prescription. And if he received -- without an accompanying physician exception certification -- a prescription calling for a brand priced above the MAC level, the pharmacist would confront a very serious professional dilemma.