

Docket No. 2006N-0061
RIN number 0910-AF13

Charging for Investigational Drugs

Geisinger Health Plan welcomes the opportunity to provide comment to FDA on the proposed amendments to the Investigational New Drug (IND) application regulation concerning charging patients for investigational new drugs. The current regulation for charging for an investigational drug is 312.7. Section 312.7(d) clearly states:

1. FDA may authorize charging for an investigational drug used in a treatment protocol or treatment IND
2. A sponsor must provide explanation why charging is necessary
3. Four conditions must be met:
 - a. Adequate enrollment in the ongoing clinical investigations under the authorized IND.
 - b. Charging must not constitute commercial marketing of a new drug
 - c. The drug must not be commercially promoted or advertised
 - d. The sponsor must be actively pursuing marketing approval.
4. The sponsor may not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development and handling of the investigational drug.

The FDA stated three situations showing a need for revising 312.7 (d).

1. Requests for charges for approved drugs in trials when the drugs must be obtained from another company. Also, charges for approved drugs used in studies by a third party(not the manufacturer) that are intended to study new uses of the approved drug or to compare two drugs.
2. In addition to allowing for charging related to treatment use when the drug is provided under a treatment IND or treatment protocol (312.7), a subpart would be added to allow for expanding access to investigational drugs for treatment use. Along with the treatment IND and treatment protocol provisions, it would add expanded access for treatment of intermediate size patient populations and for individual patients. In this regard, it is consistent with another proposal under consideration by the FDA (see Docket No 2006-0062).
3. The FDA seeks to further specify the types of costs that can be recovered.

We agree that charging for approved drugs in trials when the drugs must be obtained from another company may be appropriate. In particular, the potential benefit of studies that compare two drugs or that further define appropriate patient selection for an approved drug would be welcome trends.

We believe that the subpart that allows for charging for treatment of intermediate size patient populations and for individual patients could result in a significant financial impact. The proposal stated that the FDA believes that Executive Order 12866 does not apply because the proposed rule is not an economically significant regulatory action. It is stated that this conclusion is uncertain. The rationale for reaching this conclusion does not include a financial analysis of the costs associated with drugs. One of the reasons for allowing for charges is that the development of the investigational drug is extraordinarily expensive. Since the FDA is predicting that requests for charges will likely increase, and since the costs associated with the drugs are extraordinary, it seems likely that there would be a significant financial impact. It is unknown whether or not it would exceed the target of \$122 million per year. It seems to us that, in accordance with Executive Order 12866, it is incumbent upon the FDA to perform an economic impact analysis or to provide a better reason why it is believed that this Executive Order does not apply.

We trust that the FDA places a value on evidence before making determinations about the safety and efficacy of new drugs. We also believe that the FDA will collect and examine evidence before making determinations of policy.

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