Dated: October 11, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 95–25669 Filed 10–12–95; 1:38 pm]
BILLING CODE 4160–01–C

[Docket No. 95D–0283]

Deciding When To Submit a 510(k) for a Change to an Existing Device; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an August 1, 1995, draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The draft guidance includes a flowchart model that can be used by manufacturers in their decisionmaking to analyze whether certain changes in a device could significantly affect the safety or effectiveness of the device and, therefore, require submission of a new 510(k). The draft guidance is intended to provide direction to manufacturers, specification developers, and distributors of devices who intend to modify their device and are in the process of deciding whether the modification requires a new premarket notification submission (510(k)).

DATES: Written comments by December 15, 1995.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of the draft guidance, are available from the Division of Small Manufacturers Assistance (DSMA) Facts on Demand, Center for Devices and Radiological Health (CDRH), 1–800–899–0381. Copies of the draft guidance may also be obtained from the electronic docket administered by DSMA and are available to anyone with a video terminal or personal computer (1–800–252–1366).

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2444.

SUPPLEMENTARY INFORMATION:

I. Background

On April 8, 1994, FDA circulated for comment the first draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The draft guidance was intended to provide direction to manufacturers on deciding when to submit a new 510(k) for changes to an existing device. The April 8, 1994, draft guidance was the subject of a May 12, 1994, FDA teleconference. The April 8, 1994, draft guidance was also the subject of discussion at several trade and industry association meetings.

FDA received over 60 comments regarding the April 8, 1994, draft guidance. Based on the comments received, FDA developed an August 1, 1995, second draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' FDA is now announcing the availability of the August 1, 1995, draft guidance to elicit further public comment.

II. When to Submit a 510(k) for a Change to an Existing Device

Whenever a manufacturer of a legally marketed device decides to change the device's design or labeling, it is faced with a decision on whether to submit a 510(k). Section 807.81(a)(3) (21 CFR 807.81(a)(3)) states that a premarket notification is required for changes to a currently marketed device that ''could significantly affect the safety or effectiveness of the device.'' FDA staff have tried to define this phrase with greater accuracy, as well as the criteria contained in 21 CFR 807.81(a)(3)(i) and (ii) which are expressed in general terms using adjectives such as ''major'' and ''significant,'' because they can sometimes lead to subjective interpretation.

FDA's previous attempts to develop guidance in this area have not been entirely successful, and manufacturers have frequently expressed the need for more definitive guidance. FDA has now developed such guidance and is making it available as a draft for public comment.

III. The Draft Guidance

The draft guidance has been developed to provide aid to manufacturers, specification developers, and distributors of class I, class II, or preamendment (devices in commercial distribution before May 28, 1976) class III devices for which premarket approval has not yet been required under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) who intend to modify their device and are in the process of deciding whether the modification meets the regulatory threshold for submitting a new 510(k). Whenever possible, the draft guidance attempts to incorporate existing guidance and policy regarding when a 510(k) is necessary for modifications to a currently legally-marketed device.

The draft guidance is not intended to supplant existing definitive guidance for modifications to specific devices, i.e., for daily wear contact lenses. Moreover, the draft guidance is not intended to apply to device kits, nor is it intended to apply to combination products, such as drug/device or biologic/device combinations. The draft guidance is also not intended to address the need for submitting a 510(k) by refurbishers or remanufacturers of devices. FDA intends to develop additional guidance specific to these situations.

The types of modifications addressed in the draft guidance include labeling changes, technology or performance specifications changes, and materials changes. The basis for comparison of any changed device is the device described by a cleared 510(k) or a legally marketed pre-1976 device. That is, manufacturers may make a number of changes without having to submit a 510(k), but each time they make a change, the device they should compare it to is their most recently cleared device or their pre-1976 device, not the current legally marketed device. In effect, manufacturers need to submit a new 510(k) only when the sum of the incremental changes, taken together as though they were in fact one change, exceeds the § 807.81(a)(3) threshold, ''could significantly affect the safety or effectiveness of the device.''

According to the draft guidance, because many simultaneous changes may be considered in the evolution of device design, each type of change should be assessed separately and, when any one change leads the manufacturer to decide to submit a 510(k), then a 510(k) incorporating all

the current changes and comparing the new device to the originally cleared device, or one marketed prior to May 28, 1976, should be submitted. The new 510(k), once cleared, would form the basis of comparison for the next sequence of changes.

The draft guidance consists of a flowchart model to help manufacturers through the logic scheme necessary to arrive at a decision on when to submit a 510(k) for a change to an existing device. The flowchart includes the following three logical breakouts of changes that might be made to a device: Labeling changes, technology or performance specifications changes, and materials changes. To use the model, the questions posed in the flowchart should be answered until the 510(k) holder is directed to consider submitting a 510(k), document the decisionmaking, or notify the agency of the change being effected. The last option occurs for the addition of a contraindication and the necessary documentation would constitute an administrative addition to the 510(k) currently on file.

When contemplating changes to a device, manufacturers should use the flowchart for each individual type of proposed change, e.g., performance specification change, material change, etc. If any one of the changes results in a manufacturer's decision to submit a 510(k), then the 510(k) should be submitted and should incorporate all of the intended changes, as well as a comparison to the originally cleared device described by the 510(k) currently on file with FDA. If a manufacturer's consideration of all proposed changes results in a decision merely to document the decisionmaking, it should document the application of the model along with the necessary records of the validation of changes to the device. In those circumstances where the proposed change is not addressed in the flowchart or in a device-specific guidance document, manufacturers are encouraged to contact the Office of Device Evaluation in CDRH to find out whether other, specific guidance exists or if additional help is available.

IV. Significance of a Guidance

Guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the draft guidance is not being issued under the authority of current § 10.90(b), and it does not create or confer any rights, privileges, or benefits for or on any person, nor does it operate to bind FDA or device manufacturers in any way.

V. Requests for Comments

Interested persons may, on or before December 15, 1995, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether to amend the current draft guidance document.

Dated: October 2, 1995.

Joseph A. Levitt,

Deputy Director for Regulations policy, Center for Devices and Radiological Health.

[FR Doc. 95–25502 Filed 10–13–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OACT–049–N]

RIN 0938–AH08

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1996 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae to be used to determine these amounts.

The inpatient hospital deductible will be $736. The daily coinsurance amounts will be: (a) $184 for the 61st through 90th days of hospitalization in a benefit period; (b) $368 for lifetime reserve days; and (c) $92 for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 1996.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786–6389. For case-mix analysis only: Gregory J. Savord, (410) 786–6384.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish between September 1 and September 15 of each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year.

II. Computing the Inpatient Hospital Deductible for 1996

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act). This estimate is used for updating the payment rates to hospitals for discharges in the fiscal year that begins on October 1 of the same preceding calendar year and adjusted to reflect real case mix. The adjustment to reflect real case mix is determined on the basis of the most recent case mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

For fiscal year 1996, section 1886(b)(3)(B)(i)(XI) of the Act provides that the applicable percentage increase for hospitals in all areas is the market basket percentage increase minus 2.0 percent. Section 1886(b)(3)(B)(ii)(V) of the Act provides that, for fiscal year 1996, the otherwise applicable rate-of-increase percentages (the market basket percentage increase) for hospitals that are excluded from the prospective payment system are reduced by the lesser of 1 percentage point or the percentage point difference between 10 percent and the percentage by which the hospital's allowable operating costs of inpatient hospital services for cost reporting periods beginning in fiscal year 1990 exceeds the hospital's target amount. Hospitals or distinct part hospital units with fiscal year 1990