supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act set forth requirements for changes to be described in an annual report (minor changes). Under these sections, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 7,040 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information and that it will take approximately 35 hours to prepare and submit to FDA the information for each annual report.

In the **Federal Register** of September 7, 2000 (65 FR 54279), the agency requested comments on the proposed collections of information. FDA received one comment which, disagreed with the ''hours per response'' burden. The comment estimated that it would take approximately 182 hours to prepare and submit prior approval supplements; 130 hours for changes-being effected supplements; and 50 hours for changes to be described in an annual report.

FDA has considered the comment as well as other information it has received, and it has revised the burden estimates. The estimate for preparing and submitting prior approval supplements has been increased to 150 hours, from the previous estimate of 120 hours; the estimate for changes-being-effected supplements has been increased to 95 hours, from previous estimate of 80 hours; and the estimate for changes to be described in an annual report has been increased to 35 hours, from the previous estimate of 25 hours.

The comment also recommended that FDA summarize reporting requirements in a tabular format in addition to the discussion provided in the guidance, and that flow charts should be developed to aid sponsors through the process of determining the proper reporting mechanism. The comment also stated that it would be helpful to have easy access to ''such things as inks used in CDER-approved products and GMP status.''

FDA declines to discuss these suggestions in this notice. The purpose of this notice and the September 7, 2000, notice is to obtain comments on the agency's estimates of the information collection burden that would result from the Guidance ''Changes to an Approved NDA or ANDA.'' The above comments pertain to the guidance document itself and should be directed to Docket Number 99D–0529 (see the notice announcing the availability of the guidance document that published in the **Federal Register** of November 23, 1999 (64 FR 65716).

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32614 Filed 12–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2092–N]

Medicare Program; Deductible Amount for Medigap High Deductible Policy Options for Calendar Year 2001

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

ACTION: Notice.

SUMMARY: This notice announces the annual deductible amount of $1,580 for the Medicare supplemental health insurance (Medigap) high deductible policy options for 2001. High deductible policy options are those with benefit packages classified as ''F'' or ''J'' that have a high deductible feature. The deductible amount represents the annual out-of-pocket expenses (excluding premiums) that a beneficiary who chooses one of these options must pay before the policy begins paying benefits.

EFFECTIVE DATE: January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Kathryn McCann, (410) 786–7623.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Supplemental Insurance

A Medicare supplemental, or Medigap, policy is the principal type of private health insurance that a beneficiary may purchase to cover certain costs that Medicare does not cover. The beneficiary is responsible for deductibles and coinsurance amounts for both Part A (hospital insurance) and Part B (supplementary medical insurance) of the Medicare program. In addition, Medicare generally does not cover custodial nursing home care, eyeglasses, dental care, and most outpatient prescription drugs. A beneficiary must either pay the full cost of these services, or he or she may purchase additional private health insurance to help pay these costs. Medigap policies offer coverage for some or all of the deductibles and coinsurance amounts required by Medicare. Additionally, Medigap policies may provide coverage for some services that are not covered under the Medicare program.

Section 1882 of the Social Security Act (the Act) establishes, among other things, minimum standards for Medigap policies. No Medigap policy may be issued in a State unless the policy meets one of the following criteria: (a) the Secretary has certified it as meeting Federal standards and requirements, or (b) it complies with State laws established in accordance with section 1882(b)(1) of the Act.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) amended the Act by standardizing Medigap benefits and requiring that no more than 10 Medigap benefit packages, Plans ''A'' through ''J,'' be offered nationwide. Three States (Wisconsin, Minnesota, and Massachusetts) experimented with standardizing benefits before the enactment of Federal standards. These States were permitted to keep their alternative forms of Medigap standardization, and we refer to them as the ''waivered States.''

Plan ''A'' is the basic benefit package. It covers Medicare Part A hospital coinsurance plus coverage for 365 additional days after Medicare benefits end, over the beneficiary's lifetime, Medicare Part B coinsurance (generally 20 percent of the Medicare-approved amount) or, in the case of hospital outpatient department services under a prospective payment system, the applicable copayment, and coverage for the first 3 pints of blood per year. Medigap Plans ''B'' through ''J'' contain this basic benefit package, as well as different combinations of coverage for some or all of the following benefits:

- Medicare Part A inpatient hospital deductibles.
- Skilled-nursing facility coinsurance.
- Foreign travel health emergencies, at home recovery.
- Preventive care.

• Some prescription drug coverage.
• Medicare Part B excess charges protection.

B. High Deductible Medigap Standard Policies

Section 4032 of the Balanced Budget Act of 1997 (BBA) added high deductible versions of two of the standard Medigap policies or their counterparts in the waivered States. In the three waivered States, high deductible versions of the plans that most closely approximate the benefits contained in Plans ''F'' and ''J'' are authorized by the Balanced Budget Act. Unlike the regular versions of Plans ''F'' and ''J,'' the high deductible versions of these policies do not begin paying benefits until the deductible amount is met. Amounts included in this deductible are the expenses that would ordinarily be paid by the regular version of the policy, including Medicare deductibles for Parts A and B. The Plan ''F'' deductible does not include the separate foreign travel emergency deductible of $250. The Plan ''J'' deductible does not include the plan's separate $250 prescription drug deductible or the plan's separate $250 deductible for foreign travel emergencies.

II. Provisions of This Notice

In 1998 and 1999, the high deductible amount was statutorily-defined as $1,500 in section 1882(p)(11)(C)(i) of the Act. For 2000, the high deductible amount was increased to $1,530, based on the percent increase in the Consumer Price Index (CPI) for all urban consumers for the 12-month period ending August 1999. For 2001, the high deductible amount is increased by the percent increase in the Consumer Price Index (CPI) for all urban consumers (all items, U.S. city average) for the 12-month period ending August 2000. The percent increase in the CPI for all urban consumers (all items, U.S. city average) for the 12-month period ending in August 2000 was 3.35 percent, according to the Division of Labor Statistics, Department of Labor. A 3.35 percent increase in $1,530 is $1,581.26. (This figure can also be found by dividing the August 2000 CPI (172.7) by the August 1999 CPI (167.1), which equals 1.0335129. Multiplying this number by the 2000 deductible ($1,530) equals 1581.27 which, rounded to the nearest $10 multiple, is $1,580. Section 1882(p)(11)(C)(ii) of the Act stipulates that this amount ($1,581.26) be rounded to the nearest multiple of $10 to find the high deductible amount for the subsequent year. After rounding $1,581.26 to the nearest $10 multiple, the 2001 deductible for the Medigap high deductible options is $1,580. 2

Authority: Section 1882 of the Social Security Act.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

November 6, 2000.

Michael M. Hash

Acting Administrator, Health Care Financing Administration

[FR Doc. 00–32441 Filed 12–20–00; 8:45 am]

BILLING CODE 4120–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1172–N]

Medicare Program; January 10, 2001, Meeting of the Advisory Panel on Medicare Education

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting on January 10, 2001 of the Advisory Panel on Medicare Education (the Panel). This Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services (HHS) and the Administrator of the Health Care Financing Administration (HCFA) on opportunities for HCFA to optimize the effectiveness of the National Medicare Education Program and other HCFA programs that help Medicare beneficiaries understand Medicare and the range of Medicare options available with the passage of the Medicare+Choice Program. The Panel meeting is open to the public.

DATES: The meeting is scheduled for Wednesday, January 10, 2001, from 8 a.m. e.s.t until 5:15 p.m. e.s.t.

ADDRESSES: The meeting will be held at the Madison Hotel, at 1177 15th Street, NW., Washington, DC 20005, Telephone: (202) 862–1600.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Caliman, Public Affairs Specialist, Partnership Development Group, Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, S2–23–05, Baltimore, MD, 21244–1850, (410) 786–5052. Please refer to the HCFA Advisory Committees Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (http://www.hcfa.gov/events/apme/homepage.htm) for additional information and updates on committee activities, or by contacting Ms. Caliman via E-mail at APME@hcfa.gov. Press inquiries are handled through the HCFA Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: The Federal Advisory Committee Act (5 U.S.C. App. 2, Sec. 9(a)), Public Law 92–463, grants to the Secretary the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999). The Advisory Panel on Medicare Education advises us on opportunities to enhance the effectiveness of consumer education materials serving the Medicare program.

The goals of the Panel are as follows:

• Developing and implementing a national Medicare education program that describes the options for selecting a health plan under Medicare.

• Enhancing the Federal Government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.

• Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.

• Assembling an information base of best practices for helping consumers evaluate health plan options, and for building a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Diane Archer, J.D., President, Medicare Rights Center; David Baldridge, Executive Director, National Indian Council on Aging; Bruce Bradley, M.B.A., Director, Managed Care Plans, General Motors Corporation; Carol Cronin, Chairperson, Advisory Panel on Medicare Education; Joyce Dubow, M.U.P., Senior Policy Advisor, Public Policy Institute, AARP; Jennie Chin Hansen, Executive Director, On Lok Senior Services; Elmer Huerta, M.D., M.P.H., Director, Cancer Risk and Assessment Center, Washington Hospital Center; Bonita Kallestad, J.D., M.S., Western Minnesota Legal Services, Mid Minnesota Legal Assistance; Steven Larsen, J.D., M.A., Maryland Insurance Commissioner, Maryland Insurance Administration; Brian Lindberg, M.M.H.S., Executive Director, Consumer Coalition for Quality Health Care; Heidi Margulis, B.A., Vice President, Government Affairs, Humana, Inc.; Patricia Neuman, Sc.D., Director,