public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both. The draft guidance is being distributed for comment purposes in accordance with FDA's GGP's (62 FR 8961, February 27, 1997); the draft guidance has been designated as Level 1 guidance.

Interested persons may, on or before December 7, 1998, submit written comments regarding the draft guidance and report to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance, report, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. After consideration of any comments received in response to this notice, FDA will revise the draft guidance as appropriate and will announce its availability in the **Federal Register**.

An electronic version of the draft guidance and report are available on the Internet using the World Wide Web (WWW) at http://vm.cfsan.fda.gov under the heading ''Biotechnology.''

Dated: August 28, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98–24072 Filed 9–4–98; 8:45 am]

**BILLING CODE 4160–01–F**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**[HCFA–1045–N]**

**RIN 0938–AJ16**

**Medicare Program: Request for Public Comments on Implementation of Risk Adjusted Payment for the Medicare+Choice Program and Announcement of Public Meeting**

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

**ACTION:** Solicitation of comments; announcement of meeting.

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**SUMMARY:** This notice solicits further public comments on issues related to the implementation of risk adjusted payment for Medicare+Choice organizations. Section 1853(a)(3) of the Social Security Act (the Act) requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on

health status and demographic factors for payments no later than January 1, 2000. The methodology is to apply uniformly to all Medicare+Choice plans. This notice outlines our proposed approach to implementing risk adjusted payment.

In order to carry out risk adjustment, section 1853(a)(3) of the Act also requires Medicare+Choice organizations, as well as other organizations with risk sharing contracts, to submit encounter data. Inpatient hospital data are required for discharges on or after July 1, 1997. Other data, as the Secretary deems necessary, may be required beginning July 1998.

The Medicare+Choice interim final rule published on June 26, 1998 (63 FR 34968) describes the general process for the collection of encounter data. We also included a schedule for the collection of additional encounter data. Physician, outpatient hospital, skilled nursing facility, and home health data will be collected no earlier than October 1, 1999, and all other data we deem necessary no earlier than October 1, 2000. Given any start date, comprehensive risk adjustment will be made about three years after the year of initial collection of outpatient hospital and physician encounter data. Comments on the process for encounter data collection are requested in that interim final rule. We intend to consider comments received in response to this solicitation as we develop the final methodology for implementation of risk adjustment.

This notice also informs the public of a meeting on September 17, 1998, to discuss risk adjustment and the collection of encounter data. The meeting will be held at the Health Care Financing Administration headquarters, located at 7500 Security Boulevard, Baltimore, MD, beginning at 8:30 a.m. Additional materials on the risk adjustment model will be available on or after October 15, 1998, and may be requested in writing from Chapin Wilson, Health Care Financing Administration, Department of Health and Human Services, 200 Independence Avenue, S.W., Room 435–H, Washington, DC 20201.

**DATES:** We request that comments be submitted on or before October 6, 1998.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1045–N, P.O. Box 26688, Baltimore, MD 21207.

If you prefer you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1045–N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone (202) 686–7890).

**FOR FURTHER INFORMATION CONTACT:** Cynthia Tudor, (410) 786–6499.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Since 1985, Medicare payments to risk contracting Health Maintenance Organizations (HMOs) for aged and disabled beneficiaries living in a given county have been based on actuarial estimates of the per capita cost Medicare incurs paying claims on a fee-for-service (FFS) basis in that county. (Medicare's costs in paying claims for beneficiaries with end-stage renal disease are not considered in these county estimates, but are treated separately on a statewide basis.) These county estimates have been adjusted for the demographic composition of that county (age, gender, Medicaid eligibility status, and institutional status) in order to produce a figure representing the costs that would be incurred by Medicare on behalf of an average Medicare beneficiary in the county. These county per capita payment rates, adjusted for the average beneficiary, have been published annually as the county rate book. Prior to January 1998, actual payments for a given HMO enrollee were based on this county rate book amount, adjusted by demographic factors associated with each enrollee. Again, the demographic factors have been age, gender, Medicaid eligibility, and institutional status. This methodology is known as the ''Adjusted Average Per Capita Cost'' (AAPCC) methodology, and HMOs with Medicare contracts under section 1876 of the Social Security Act (the Act) were paid on this basis between 1985 and 1997.

In enacting the new Part C of Title XVIII to create the Medicare+Choice program, the Congress provided, a new section 1853 of the Act, for a new methodology for paying organizations that enter into Medicare+Choice contracts. Under this new methodology, the equivalent of the above-described county rate book (that is, the county-wide amount that is adjusted by an individual enrollee's demographic status to determine the final payment amount) is based on the greatest of three amounts. The first amount is a new blended payment rate methodology that would combine the area specific amounts with national data and would be subject to other adjustments. The second amount is a new minimum specified rate amount (for example, $367 per month per enrollee in 1998). The third amount is based on a 2 percent increase over the prior year's rates, with the rate book for 1997 serving as the baseline. As in the case of the AAPCC methodology described above, the county rates under section 1853 of the Act, are adjusted for the demographic status of each enrollee.

Under section 1876(k)(3) of the Act, the new Medicare+Choice payment methodology under section 1853 of the Act applies to existing HMO contracts under section 1876 for 1998, and to Medicare+Choice plans beginning in 1999.

Section 1853(a)(3) of the Act requires the Secretary to develop and implement a new risk adjustment methodology to be used to adjust the county-wide rates under section 1853 of the Act to reflect the expected relative health status of each enrollee. This new methodology, which must be implemented by January 1, 2000, would replace the current method of adjusting county-wide rates based on the four demographic factors of age, gender, Medicaid eligibility, and institutional status. The goal is to pay Medicare+Choice organizations based on better estimates of health care costs of the population they enroll (relative to the FFS population).

While the Medicare+Choice legislation mandates the implementation of risk adjustment in general, the legislation provides the Secretary with broad discretion to develop a risk adjustment methodology that would ''account for variations in per capita costs based on health status and other demographic factors.'' Because Medicare+Choice legislation does not allow for the collection of any data other than inpatient hospital data (in the near term), we are constrained initially to using a model that requires only inpatient data. We are currently receiving these data. In previous public

meetings on encounter data requirements, organizations have been briefed on the Principal Inpatient Diagnostic Cost Group (PIP–DCG), created by HHS-sponsored researchers at Health Economics Research, Inc., and Boston and Brandeis. This is the only risk adjuster model that has been developed to run solely on inpatient data. The model was recently updated using 1995 and 1996 Medicare data.

The remainder of this notice outlines our proposed approach for implementation of risk adjusted payments on January 1, 2000, discussing both the risk adjustment methodology and the proposed risk adjustment payment model. In the development of all risk adjustment payment models, there are two tasks that must be performed: (1) The estimation of the risk adjustment model, and (2) application of the risk adjustment model to a payment system. The estimation of the PIP–DCG model is described first.

### A. The Principal In-Patient Diagnostic Cost Group (PIP–DCG) Model

In constructing a risk adjustment model, it is important to determine which set of conditions should be used to adjust payments. Under the current payment system, all enrollees are placed in a base group paid according to demographic characteristics. In this risk adjustment system, all conditions that appear as inpatient principal diagnoses are candidates for adjusting payments. The base payment category decreases as more conditions are placed into separate disease groups. Because an inpatient hospital-based system depends on a person's site of service, only a subset of conditions should be recognized for changing payments. That is, the system should recognize admissions for which inpatient care is most frequently appropriate. For example, admissions for diseases most commonly treated on an outpatient basis should remain in the base group and should not be used for adjustment.

The PIP–DCG model was estimated using diagnostic information for Medicare FFS enrollees from inpatient hospital stays during calendar year 1995. The sample used in the estimation analyses consisted of individuals included in the 5-percent sample of Medicare beneficiaries who were alive and enrolled in Medicare during all of 1995, and on January 1, 1996. Beneficiaries with certain characteristics (for example, HMO enrollees and end-stage renal disease enrollees, new Medicare eligibles in 1996) were excluded from the analyses. In general, these exclusions were made to increase confidence that a complete set of

Medicare claims for each beneficiary in the sample data set was included in the model development. The final estimation data set included 1.4 million Medicare beneficiaries.

While the PIP–DCG model uses only inpatient diagnoses in creating the risk adjustment classification system, the model predicts total expected costs for the following year across multiple sites of services. Consequently, all Medicare expenditures, other than those for hospice care, were included in the calculation. Medicare expenditures for hospice care were not included because Medicare+Choice organizations are not responsible for hospice care. The model was estimated assuming no time lag between the base year (diagnostic information) and the predicted expenditures; that is, calendar year 1995 beneficiary diagnoses were used to predict calendar year 1996 expenditures.

1. From Diagnosis Groups (DxGroups) to PIP–DCGs

The risk adjustment model estimation process begins with a classification system, forming the inherent logic of the model. For the PIP–DCG model, diagnoses are classified into DxGroups based on the principal inpatient diagnosis. The DxGroups comprise an exhaustive classification of all valid International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) diagnostic codes. For example, DxGroup 1, Central Nervous System Infections, includes ICD–9–CM diagnostic codes for such conditions as encephalitis and meningitis. The primary criteria in forming the DxGroups were clinical coherence and an adequate sample size to estimate average expenditures. Beneficiaries with multiple different inpatient diagnoses could have multiple hospital stays, and would initially be placed in multiple DxGroups.

Next, DxGroups were aggregated into payment groups, or PIP–DCGs, using a sorting algorithm that ranked DxGroups based on 1996 actual expenditures. For example, DxGroup 7 (Metastatic Cancer with a mean future expenditure of $26,331) was placed in PIP–DCG 26. Highest expenditure DxGroups were grouped into the ''highest'' PIP–DCG. Once beneficiaries with the highest costs were placed into a DxGroup, those beneficiaries and all their associated expenditures were removed from the data for other DxGroups and then the DxGroups were re-ranked. The DxGroups with the next most costly diagnoses were grouped into the next highest numbered PIP–DCG, and those beneficiaries were removed from the

remaining DxGroups. The process was repeated until each beneficiary and his or her expenditures were assigned to a single PIP–DCG group. Beneficiaries with multiple inpatient diagnoses were placed in their highest expenditure PIP–DCG group.

In this way, each PIP–DCG group was defined according to average total expenditures for beneficiaries with inpatient diagnoses, categorized and sorted using the DxGroups rather than diagnosis by diagnosis. Based upon this sorting algorithm, more than 20 initial PIP–DCGs were defined. Lower average expenditure PIP–DCG groups had lower cost ranges (or intervals), while the highest average expenditure PIP–DCG groups had wider ranges.[1]

### 2. Modifications to the PIP–DCG Model

After the initial sorting of DxGroups into PIP–DCG groups was complete, a clinical panel reviewed the placement of the DxGroups and their resulting predicted expenditures, to determine the appropriateness of their application in a payment model. Through this process, 75 DxGroups (covering about 1/3 of the admissions) were identified as: (1) Representing only a minor or transitory disease or disorder, not clinically likely to result in significant future medical costs, (2) rarely the main cause of an inpatient stay, or (3) vague or ambiguous. These groups, as recommended by the clinical panel, were identified as those most likely to result in inconsistent or inappropriate reimbursements and were placed (with their associated expenditures) in the base payment category (for which the payment is a function of demographic factors). Examples of these groups include the DxGroup for fluid/electrolyte disorders and malnutrition. Though the treatment for individuals with this diagnoses are often quite costly in the following year, the diagnosis is clinically vague and, therefore, represented a likely target for coding ''creep.'' The clinical panel concluded that many of the sickest individuals with this diagnosis were likely to have another hospitalization

that would trigger appropriate increased reimbursements. Then, the remaining DxGroups were resorted and placed into revised DCGs for the payment model. A total of 10 PIP–DCGs (above the base payment category) are included in the current model.

As a second strategy to ensure consistent and appropriate payment levels, beneficiary diagnoses reported as a result of a short hospital stay (1 day or less) were left in the base payment category. Since the majority of 1-day stays are for diagnoses already assigned to the base group, the effect on payment is small. Also, short stays are often indicative of less serious, and, hence, less costly cases. It is important to note that these modifications do not mean that these expenditures have been excluded from the model. Rather, the payments associated with these diseases are captured in increased payments for the base payment category, where the majority of enrollees are paid based on demographic factors.

Under the proposed PIP–DCG model, beneficiaries who are hospitalized for chemotherapy (V58.1 and V66.2) were treated as exceptions. These codes are indicators of a treatment method, rather than a particular disease. Recognizing, however, that Medicare's current inpatient coding rules require that the diagnoses for beneficiaries who are hospitalized for chemotherapy must be coded using these V-codes as the principal diagnoses, the most appropriate PIP–DCG group for these beneficiaries would be assigned based on the type of cancer, using a secondary diagnosis. A model will be estimated that uses secondary diagnoses to determine risk scores for hospitalized beneficiaries that were assigned chemotherapy V-codes (as defined above). This modification could be made for payment in calendar year 2000. The model described in this notice has left these admissions in the base group.

### 3. Addition of Demographic and Other Factors

The next phase in the estimation of the model was the creation of demographic variables (age, sex, and disability status) for the PIP–DCG groups. In this phase of the calibration, 24 age and sex groupings were created. Separate groupings were created for males and females, by 5-year age increments, except where numbers were too small to get good estimates (that is, age group 0 through 34 and greater than 94 for males and females).

Separate parameters were also included to estimate the unique cost effects of whether an aged beneficiary

was formerly eligible because of a disability, and whether an aged or disabled beneficiary is eligible for Medicaid. The estimated adjustments for the demographic categories are the same irrespective of which PIP–DCG an enrollee falls into. The Medicaid adjustment, however, depends on a person's status as aged or disabled.

New enrollees to Medicare, for whom there are no claims history, will be assigned a score based on a separate HCFA analysis of actual new enrollee expenditures. At this time, a separate parameter is not anticipated for the institutionalized because institutional status is not needed as an indicator of high Medicare utilization. Under the demographically adjusted system, institutional status was an indicator of a beneficiary with relatively poor health status. It, therefore, increased payments over the age and sex based amounts. The risk adjuster model has health status measures built in, and on the average, compensates for poor health status. In fact, preliminary estimates indicate that after accounting for inpatient hospital admissions, the institutional adjustment would be negative. Adjustments for the working-aged will be made in a manner similar to the current system. As a last step during the estimation, expenditures were adjusted to create an estimate of annual payments as if each beneficiary had been alive and enrolled for the entire year. This is equivalent to an expenditure per month measure. Estimation of the incremental costs associated with each of the variables (for example, demographics, DCGs) was made by the linear regression technique, which takes account of all the variables that apply to an individual.

### 4. The Current PIP–DCG Model

The current PIP–DCG model contains a total of 37 parameters (10 PIP–DCGs and 27 demographic or Medicaid factors). The model will continue to be refined over the next few months. While there are a number of ways to assess the ''accuracy'' of the model, payment for different groups of beneficiaries is improved with risk adjustment compared to the application of a demographic only model. Preliminary coefficients for the PIP–DCG model are presented in Table 1. The current placements of DxGroups into PIP–DCG groups are shown in Table 2. The next section of this notice details how we are proposing to use the PIP–DCG model in the Medicare+Choice payment system as of January 1, 2000.

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[1] The PIP–DCG groupings were further refined using a number of criteria. First, each original PIP–DCG group remained in the final payment model only if it contained at least 1,000 beneficiaries from the original sample; this minimum sample size was defined to assure stability of estimated payments in the final model. If sample sizes were smaller than 1,000, the potential PIP–DCG was expanded to include DxGroups with average expenditures in the next lower range until the sample size criteria was satisfied. If at any time during the sorting algorithm a DxGroup had fewer than 50 beneficiaries assigned to it, it was assigned to the base payment category. This base payment category also included all beneficiaries (and expenditures) for whom there was no inpatient diagnosis during 1995.

*B. Proposed Payment System Application of the PIP–DCG Model*

In its basic form, the PIP–DCG model is an algorithm that uses base year inpatient diagnoses, along with demographic factors and Medicaid eligibility, to predict total health spending in the following year. In applying the PIP–DCG model to risk adjusted payments for the Medicare+Choice program, however, the model will be used to determine relative risk scores. These relative risk scores will be used, in place of the current demographic factors, to adjust county rate book payments for the relative health status of the individual enrollee.

1. Estimating Beneficiary Relative Risk Factors

The PIP–DCG model was developed to be ''additive'', meaning that incremental dollars are added together based on each beneficiary's characteristics. Referring to Table 3, the following examples illustrate how the PIP–DCG model will be used for estimating relative risk factors.

A beneficiary is placed in a PIP–DCG group, based on inpatient diagnoses reported. In this example, ''Beneficiary A'' was hospitalized twice during the base year. The diagnoses reported were Asthma (PIP–DCG 8) and Lung Cancer (PIP–DCG 18). The highest PIP–DCG category then for this beneficiary is PIP–DCG 18, which carries with it an estimated future year expenditure of $12,883. The beneficiary is also placed in the appropriate demographic groups. In this case, Beneficiary A is male, aged 82. This age group carries an estimated expenditure of $5,617. In addition, Beneficiary A had originally been Medicare eligible because of a disability (which carries an incremental expenditure of $2,381), but is not eligible for Medicaid (no expenditure increment). Adding together these increments based on the PIP–DCG model, the predicted expenditures for this beneficiary are $20,881.

As another example, consider ''Beneficiary B.'' Beneficiary B had no inpatient admissions during the base year. Therefore, no specific PIP–DCG increment is added; expenditures for non-hospitalized beneficiaries are included in the demographic factors. Beneficiary B is placed in the appropriate age and sex grouping; in this case, female aged 72, which carries a predicted expenditure of $3,118. Beneficiary B is also placed in the Aged with Medicaid eligibility group, which adds $2,124 to her annual predicted expenditures. Since she has never been disabled, no additional expenditures are

added. Therefore, total annual predicted expenditures for Beneficiary B are $5,242.

Because Medicare+Choice program payments are based on the county-wide rates determined under section 1853(c) of the Act, the predicted annual expenditures described above will be converted to relative risk scores. This is accomplished by dividing the predicted expenditures for each beneficiary by the national average predicted expenditure ($5,300). Individuals whose risk scores are equal to 1.00 are ''average.'' In the examples described above, Beneficiary A's relative risk score is 3.9 (indicating a high expected cost individual), while Beneficiary B's relative risk score is 0.99 (indicating a slightly lower than average risk individual).

After Medicare+Choice organizations submit inpatient hospital encounter data, we will use the demographic information and diagnostic information from all Medicare+Choice organizations a beneficiary may have joined and from FFS to determine the appropriate risk factor for each beneficiary. When a Medicare+Choice organization forwards enrollment information to us, we, in turn, will send the Medicare+Choice organization the appropriate risk factor, as well as the resultant payment. Because the risk factor is computed for each individual beneficiary, the factor follows that beneficiary. In addition, since all beneficiaries will have risk factors, information will be immediately available for payment purposes as beneficiaries move among Medicare+Choice organizations.

Risk adjustment factors for new Medicare beneficiaries (for whom health status information) is not available will be based on demographic information only. Examples of persons using the demographic model are new 65-year-olds and new Medicare disabled individuals. Similar to the current system, a ''demographic only'' model is being developed that will be used to determine the risk adjustment factors for these beneficiaries.

2. Risk Adjusted Payment Model

To determine risk adjusted monthly payment amounts for each Medicare+Choice enrollee, individual risk factors (described above) will be multiplied by the appropriate payment rate for the county determined under section 1853(c) of the Act. Beginning with the implementation of risk adjustment, the separate aged and disabled rate books (incorporating combined Medicare Parts A and B) will be combined. Risk adjusted payments will be made using a single, combined Medicare+Choice county rate book. This

change will be made because there is a single risk adjustment methodology for the entire Medicare population (excluding persons with end-stage renal disease).

In addition to combining the current aged and disabled county rate books into a single combined county rate book, an adjustment to these rate book amounts will be required before applying the risk adjustment factors discussed above. This adjustment, or re-scaling factor, is necessary in order to account for the fact that the existing county rate book already accounts for demographic factors that are addressed, in a more precise way, in the risk adjustment factors we will be using. If the PIP–DCG model risk adjustment factors were applied to unadjusted county rate book amounts, this would create unintended distortions that would produce adjustments inconsistent with Congress' mandate in section 1853(c) of the Act. The application of the rescaling factor we are proposing would in effect translate the rate book amounts into the same language used under the risk adjustment methodology, so that we are not comparing ''apples to oranges.'' As a result of rescaling, payment for a person with the average risk score in a county would be the same as payment for a person with the average demographic score in that county. (However, a person with the average demographic score does not necessarily have the average risk score.) To the extent that an organization enrolls sicker people, the organization will receive higher payments.

*C. Summary of HCFA's Proposed Approach for 2000*

The proposed approach we will use to meet the year 2000 mandate for risk adjusted payments will—

(1) Be based on inpatient data;

(2) Utilize a prospective PIP–DCG risk adjuster to estimate relative beneficiary risk scores;

(3) Apply a re-scaling factor to address inconsistencies between demographic factors in the rate book and new risk adjusters;

(4) Apply individual enrollee risk scores in determining fully capitated payments;

(5) Include the auditing of medical records to validate encounter data;

(6) Implement processes to collect encounter data on additional services; and

(7) Continue to refine the risk adjustment system based on ongoing research.

*D. Other Issues*

In addition to comments on the proposed risk adjustment approach, we are interested in receiving responses to the following questions: (1) Under one possible implementation approach we have considered, a Medicare+Choice organization would be paid initially based on estimates of the number of enrollees the organization has in a given risk factor category. These estimates would be based on the most recently available data (probably July 1998 through June 1999). Once more current data (from January 1999 through December 1999) became available in July 2000, a retroactive adjustment would be made pursuant to section 1853(a)(2) of the Act ''to take into account any difference between the actual number of individuals enrolled'' in a given risk category, and the ''number of such individuals estimated to be so enrolled when the advance payment was determined.'' These adjustments would be made retroactive to January 2000. This would be consistent with our longstanding practice of making retroactive adjustments to reflect the actual number of enrollees in a current demographic category (such as institutional status, end-stage renal disease status, dual eligible status, or working aged status) when this number differs from the number of enrollees estimated to be in any such category at the time payments were initially made.

An alternative approach is to use data from an earlier period (for example, July 1, 1998 through June 30, 1999) to determine the risk factor for enrollees and payments to Medicare+Choice organizations for calendar year 2000. Using data from an earlier time period introduces some error into the estimates, but we do not believe it introduces any systematic bias. Note that implementation of this alternative model solves the problem of basing the payments to a plan on the estimated

number of enrollees in a given risk factor category, which would require a retroactive adjustment as described above. Assuming a relatively large and stable population for a plan, aggregate payments under this approach are not likely to differ from aggregate payments using a method requiring this type of retroactive payment adjustment. However, on an individual basis, using data from an earlier time period lengthens the time between a hospital stay for an enrollee and compensation to the organization for the future predicted cost of that illness.

Given these issues, what problems are Medicare+Choice organizations likely to encounter with retroactive payment adjustments? Conversely, if data from an earlier time period were used, what problems are organizations likely to encounter?

(2) The Secretary is required to announce the annual Medicare+Choice capitation rate for each Medicare+Choice payment area and the risk and other factors to be used in adjusting such rates by March 1 of the year preceding the payment year. In addition, at least 45 days prior to the annual announcement of capitation rates, the Secretary shall provide notice to Medicare+Choice organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement.

The implementation of risk adjustment will alter the methodology for calculating rates for each Medicare+Choice payment area. Given the proposed changes, what types of information should be included in the 45-day notice and the annual announcement to assist Medicare+Choice organizations in planning for risk adjusted payments?

(3) What types of problems are Medicare+Choice organizations likely to encounter as capitation payments are changed from a demographic only basis to a health status adjusted basis? How

should we address these problems, especially for small plans, rural plans, and start up plans? While we are currently processing the inpatient hospital data for managed care enrollees, we note that we will be unable to model the financial impact of the risk adjustment methodology until we have completed the processing of these data and have assigned risk scores to plans enrollees.

**II. September 17, 1998, Public Meeting**

In addition to seeking written comments from the public, we will hold a public meeting on September 17, 1998, at HCFA, 7500 Security Boulevard, Baltimore, MD. The purpose of this meeting will be to discuss issues and concerns from potential Medicare+Choice organizations, organizations contracting under section 1876 of the Act, providers, beneficiaries, and other interested parties on the implementation of risk adjusted payment. The collection and auditing of encounter data, which was described in the Medicare+Choice interim final rule published on June 26, 1998, in the **Federal Register**, will also be addressed in this meeting. The agenda for the meeting is likely to cover the following topics:

• Background on the Principal Inpatient Diagnostic Cost Group (PIP–DCG) risk adjustment model.
• Changes to the payment rates.
• Application of the risk adjustment model for payment in CY 2000.
• Description of the overall risk adjustment implementation process.
• Auditing of encounter data.
• Collection of additional encounter data.

Comments on the proposed agenda are welcome. Further information on the meeting can be obtained from Chapin Wilson, (202) 690–7874.

In accordance with E.O. 12866, this notice was reviewed by the Office of Management and Budget.

TABLE 1.—CURRENT PIP–DCG MODEL

| | |
| --- | --- |
| Number of Observations | 1,401,274 |
| R–Squared | 0.058718 |
| Dependent Variable Mean | $5,300 |
| Root Mean Square Error | 14,256 |
| Model Parameters | 37 |

| Base Payment Categories | Payment In-crement |
| --- | --- |
| Male: Aged 0–34 | 1,255 |
| Male: 35–44 | 1,940 |
| Male: 45–54 | 2,654 |
| Male: 55–59 | 3,350 |
| Male: 60–64 | 3,970 |
| Male: 65–69 | 2,792 |

TABLE 1.—CURRENT PIP–DCG MODEL—Continued

| Base Payment Categories | Payment Increment |
|---|---:|
| Male: 70–74 | 3,702 |
| Male: 75–79 | 4,738 |
| Male: 80–84 | 5,617 |
| Male: 85–89 | 6,562 |
| Male: 90–94 | 7,209 |
| Male: 95+ | 7,189 |
| Female: 0–34 | 1,345 |
| Female: 35–44 | 2,167 |
| Female: 45–54 | 2,763 |
| Female: 55–59 | 3,647 |
| Female: 60–64 | 4,673 |
| Female: 65–69 | 2,439 |
| Female: 70–74 | 3,118 |
| Female: 75–79 | 3,994 |
| Female: 80–84 | 4,768 |
| Female: 85–89 | 5,592 |
| Female: 90–94 | 5,855 |
| Female: 95+ | 5,466 |
| **Other Demographic Factors** | |
| Previously Disabled | 2,381 |
| Medicaid, Medicare Aged | 2,124 |
| Medicaid, Medicare Disabled | 1,744 |
| **PIP–DCGs** | |
| PIP–DCG 6 | 2,265 |
| PIP–DCG 8 | 4,406 |
| PIP–DCG 10 | 5,829 |
| PIP–DCG 12 | 7,950 |
| PIP–DCG 14 | 9,946 |
| PIP–DCG 18 | 12,883 |
| PIP–DCG 20 | 16,346 |
| PIP–DCG 23 | 18,950 |
| PIP–DCG 26 | 21,881 |
| PIP–DCG 29 | 29,317 |

Notes: PIP–DCG 4 is combined with the demographic factors, and includes those with no hospitalizations, modified or certain low-cost admissions. Diagnoses from hospital stays of less than two days are not used in assigning PIP–DCGS.

TABLE 2.—DIAGNOSES (DXGROUPS) INCLUDED IN EACH PIP–DCG—CURRENT PAYMENT MODEL

| | | |
|---|---:|---|
| PIP–DCG 6: | | |
| DxGroup | 18 | Cancer of Prostate/Testis/Male Genital Organs. |
| | 14 | Breast Cancer. |
| PIP–DCG 8: | | |
| DxGroup | 82 | Acute Myocardial Infarction. |
| | 146 | Pelvic Fracture. |
| | 145 | Fractures of Skull/Face. |
| | 77 | Valvular and Rheumatic Heart Disease. |
| | 86 | Atrial Arrhythmia. |
| | 84 | Angina Pectoris. |
| | 80 | Coronary Atherosclerosis. |
| | 92 | Precerebral Arterial Occlusion. |
| | 16 | Cancer of Uterus/Cervix/Female Genital Organs. |
| | 79 | Hypertension, Complicated. |
| | 36 | Peptic Ulcer. |
| | 110 | Asthma. |
| | 96 | Aortic and Other Arterial Aneurysm. |
| | 153 | Brain Injury. |
| | 1 | Central Nervous System Infections. |
| | 39 | Abdominal Hernia, Complicated. |
| | 64 | Alcohol/Drug Dependence. |
| PIP–DCG 10: | | |
| DxGroup | 109 | Bacterial Pneumonia. |
| | 42 | Gastrointestinal Obstruction/Perforation. |
| | 143 | Vertebral Fracture Without Spinal Cord Injury. |
| | 21 | Other Cancers. |
| | 4 | Tuberculosis. |
| | 97 | Thromboembolic Vascular Disease. |
| | 59 | Schizophrenic Disorders. |

TABLE 2.—DIAGNOSES (DxGROUPS) INCLUDED IN EACH PIP–DCG—CURRENT PAYMENT MODEL—Continued

|  |  |  |
|---|---|---|
|  | 11 | Colon Cancer. |
|  | 116 | Kidney Infection. |
|  | 83 | Unstable Angina. |
|  | 94 | Transient Cerebral Ischemia. |
|  | 81 | Post-Myocardia Infarction. |
|  | 150 | Internal Injuries/Traumatic Amputations/Third Degree Burns. |
|  | 32 | Pancreatitis/Other Pancreatic Disorders. |
|  | 147 | Hip Fracture. |
|  | 158 | Artificial Opening of Gastrointestinal Tract Status. |
| PIP–DCG 12: |  |  |
| DxGroup ............................................ | 91 | Cerebral Hemorrhage. |
|  | 93 | Stroke. |
|  | 56 | Dementia. |
|  | 98 | Peripheral Vascular Disease. |
|  | 41 | Inflammatory Bowel Disease. |
|  | 22 | Benign Brain/Nervous System Neoplasm. |
|  | 48 | Rheumatoid Arthritis and Connective Tissue Disease. |
|  | 49 | Bone/Joint Infections/Necrosis. |
|  | 19 | Cancer of Bladder, Kidney, Urinary Organs. |
|  | 45 | Gastrointestinal Hemorrhage. |
|  | 87 | Paroxysmal Ventricular Tachycardia. |
|  | 133 | Cellulitis and Bullous Skin Disorders. |
|  | 57 | Drug/Alcohol Psychoses. |
| PIP–DCG 14: |  |  |
| DxGroup ............................................ | 66 | Personality Disorders. |
|  | 29 | Adrenal Gland, Metabolic Disorders. |
|  | 70 | Degenerative Neurologic Disorders. |
|  | 2 | Septicemia/Shock. |
|  | 144 | Spinal Cord Injury. |
|  | 58 | Delirium/Hallucinations. |
|  | 61 | Paranoia and Other Psychoses. |
|  | 63 | Anxiety Disorders. |
|  | 73 | Epilepsy and Other Seizure Disorders. |
|  | 10 | Stomach, Small Bowel, Other Digestive Cancer. |
|  | 12 | Rectal Cancer. |
|  | 26 | Diabetes with Acute Complications/Hypoglycemic Coma. |
|  | 113 | Pleural Effusion/Pneumothorax/Empyema. |
|  | 60 | Major Depression. |
| PIP–DCG 18: |  |  |
| DxGroup ............................................ | 34 | Cirrhosis, Other Liver Disorders. |
|  | 72 | Paralytic and Other Neurologic Disorders. |
|  | 108 | Gram-Negative/Staphylococcus Pneumonia. |
|  | 111 | Pulmonary Fibrosis and Bronchiectasis. |
|  | 89 | Congestive Heart Failure. |
|  | 105 | Chronic Obstructive Pulmonary Disease. |
|  | 95 | Atherosclerosis of Major Vessel. |
|  | 13 | Lung Cancer. |
|  | 8 | Mouth/Pharynx/Larynx/Other Respiratory Cancer. |
| PIP–DCG 20: |  |  |
| DxGroup ............................................ | 112 | Aspiration Pneumonia. |
|  | 76 | Coma and Encephalopathy. |
|  | 75 | Polyneuropathy. |
|  | 17 | Cancer of Placenta/Ovary/Uterine Adnexa. |
|  | 55 | Blood/Immune Disorders. |
| PIP–DCG 23: |  |  |
| DxGroup ............................................ | 134 | Decubitus and Chronic Skin Ulcers. |
|  | 33 | End-stage Liver Disorders. |
|  | 9 | Liver/Pancreas/Esophagus Cancer. |
|  | 88 | Cardio-Respiratory Failure and Shock. |
|  | 27 | Diabetes with Chronic Complications. |
|  | 115 | Renal Failure/Nephritis. |
| PIP–DCG 26: |  |  |
| DxGroup ............................................ | 7 | Metastatic Cancer. |
| PIP–DCG 29: |  |  |
| DxGroup ............................................ | 3 | HIV/AIDS. |
|  | 15 | Blood, Lymphatic Cancers/Neoplasms. |
|  | 20 | Brain/Nervous System Cancers. |

TABLE 3.—ESTIMATING PROSPECTIVE BENEFICIARY EXPENDITURES MEAN PREDICTED EXPENDITURES = $5300

| Demographic factors base PIP–DCG | | + | PIP–DCG | + | Other factors | |
| --- | --- | --- | --- | --- | --- | --- |
| **Aged Population** | | | | | | |
| Male 65–69 ............................. | $2792 | | PIP–DCG 6 | $2265 | Previously Disabled ..................... | $2381 |
| Male 70–74 ............................. | 3702 | | PIP–DCG 8 | 4406 | Medicaid, Medicare Aged ........... | 2124 |
| Male 75–79 ............................. | 4738 | | PIP–DCG 10 | 5829 | | |
| Male 80–84 ............................. | 5617 | | PIP–DCG 12 | 7950 | | |
| Male 85–89 ............................. | 6562 | | PIP–DCG 14 | 9946 | | |
| Male 90–94 ............................. | 7209 | | PIP–DCG 18 | 12,883 | | |
| Male 95+ ................................ | 7189 | | PIP–DCG 20 | 16,346 | | |
| Female 65–69 ......................... | 2439 | | PIP–DCG 23 | 18,950 | | |
| Female 70–74 ......................... | 3118 | | PIP–DCG 26 | 21,881 | | |
| Female 75–79 ......................... | 3944 | | PIP–DCG 29 | 29,317 | | |
| Female 80–84 ......................... | 4768 | | | | | |
| Female 85–89 ......................... | 5592 | | | | | |
| Female 90–94 ......................... | 5855 | | | | | |
| Female 95+ ............................. | 5466 | | | | | |
| **Disabled Population** | | | | | | |
| Male 0–34 ............................... | 1255 | | PIP–DCG 6 | 2265 | Medicaid, Medicare Disabled ...... | 1744 |
| Male 34–44 ............................. | 1940 | | PIP–DCG 8 | 4406 | | |
| Male 45–54 ............................. | 2654 | | PIP–DCG 10 | 5829 | | |
| Male 55–59 ............................. | 3350 | | PIP–DCG12 | 7950 | | |
| Male 60–64 ............................. | 3970 | | PIP–DCG 14 | 9946 | | |
| Female 0–34 ........................... | 1345 | | PIP–DCG 18 | 12,883 | | |
| Female 34–44 ......................... | 2167 | | PIP–DCG 20 | 16,346 | | |
| Female 45–54 ......................... | 2763 | | PIP–DCG 23 | 18,950 | | |
| Female 55–59 ......................... | 3647 | | PIP–DCG 26 | 21,881 | | |
| Female 60–64 ......................... | 4673 | | PIP–DCG 29 | 29,317 | | |

(Sec. 4002 of the Balanced Budget Act of 1997 (Public Law 105–33)

Dated: August 26, 1998.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

Dated: September 1, 1998.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 98–24085 Filed 9–2–98; 4:10 pm]

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Care Financing Administration

### [HCFA–1046–N]

### RIN 0938–AJ14

## Medicare Program; September 23 and 24, 1998, Meeting of the Competitive Pricing Advisory Committee

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

**ACTION:** Notice of meeting.

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**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee. This meeting is open to the public.

**DATES:** The meeting is scheduled for September 23, 1998, from 9:00 a.m. until 5:30 p.m. and September 24, 1998, from 9:00 a.m. until 5:30 p.m.

**ADDRESSES:** The meeting will be held at the Sheraton Crystal City, 1800 Jefferson Davis Highway, Arlington, Virginia 22202.

**FOR FURTHER INFORMATION CONTACT:** Lu Zawistowich, Sc.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, Maryland 21244–1850, (410) 786–6451.

**SUPPLEMENTARY INFORMATION:** Section 4011 of the Balanced Budget Act of 1997, (BBA) (Public Law 105–33) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012 of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC). The CPAC will meet periodically to make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project.

The CPAC consists of 15 individuals who are independent actuaries; experts in competitive pricing and the administration of the Federal Employees Health Benefit Program; and representatives of health plans, insurers, employers, unions, and beneficiaries. In accordance with section 4012(a)(5) of the BBA, the CPAC shall terminate on December 31, 2004.

The CPAC held its first meeting on May 7, 1998, and its second meeting on June 24 and 25, 1998. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, HCFA; John Bertko, CEO and Senior Actuary, PM-Squared Inc.; Dave Durenberger, Senior Health Policy Fellow, University of St. Thomas and Founder of Public Policy Partners; Gary Goldstein, M.D., CEO, The Oschner Clinic; Samuel Havens, Healthcare Consultant and Chairman of Health Scope/United; Margaret Jordan, Healthcare Consultant and CEO, The Margaret Jordan Group; Chip Kahn, CEO, The Health Insurance Association of America; Cleve Killingsworth, President, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer,