Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Clinic Form 1	26	204 (12 x 17)	11/60
Laboratory Form 2	5	1,056 (12 x 88)	60/60
Laboratory Form 3	5	48 (12 x 4)	12/60

Dated: September 24, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–24436 Filed 9–28–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–47–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project: Evaluation of Viral Hepatitis B Educational Slide Materials—New—National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC). The purpose of the proposed study is to assess the usefulness of the Hepatitis B and You, an educational slide set located on the website of the Hepatitis Branch, NCID, CDC. The Hepatitis B and You educational slide set is used to educate persons about hepatitis B in general and more specifically the importance of hepatitis B vaccination to prevent perinatal transmission of hepatitis B virus (HBV). An estimated 1.25 million Americans are chronically infected with HBV and 4,000 to 5,000 die each year due to resultant cirrhosis and liver cancer. The estimated cost associated with HBV infections is $700 million a year in medical care and lost work days. The annualized total burden is 414 hours.

Form name	Number of respondents	Number of responses per respondent	Avg. buden per response (in hours)
Web	1656	1	15/60

Dated: September 24, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–24437 Filed 9–28–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1182–FN]

RIN 0938–AK75

Medicare Program; Revision of Payment Rates for End-Stage Renal Disease (ESRD) Patients Enrolled in Medicare+Choice Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice establishes a new payment methodology, effective January 2002, for beneficiaries with End-Stage Renal Disease (ESRD) who are enrolled in Medicare+Choice (M+C) plans. This methodology implements section 605 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Section 605 requires the Secretary to increase M+C ESRD payment rates, using appropriate adjustments, to reflect the demonstration rates (including the risk adjustment methodology associated with those rates) of the social health maintenance organization (SHMO) ESRD capitation demonstrations. Briefly, the methodology set forth in this final notice—

Increases the base year rates by 3 percent to reach 100 percent of fee-for-service costs as estimated for the base year for M+C purposes (this adopts the approach used under the ESRD SHMO demonstration); and

Adjusts State per capita rates by age and sex factors, in order to pay more accurately, given differences in costs among ESRD patients.

The effect of the new M+C ESRD payment methodology is to increase Medicare's fiscal year (FY) 2002 M+C ESRD payments by an estimated $35 million (for 9 months of costs, given the effective date of January 2002). M+C ESRD payment increases through FY 2006 are estimated to be $55 million for FY 2003, $55 million for FY 2004, $60 million for FY 2005, and $65 million for FY 2006.

The payment methodology set forth in this notice will govern M+C payments for enrollees with ESRD in 2002.

EFFECTIVE DATE: This final notice is effective January 1, 2002.

For information on ordering copies of the **Federal Register** containing this document and electronic access, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anne Hornsby, (410) 786–1181.

SUPPLEMENTARY INFORMATION:

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I. Background

Section 605 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554, enacted on December 21, 2000) (BIPA) amends section 1853(a)(1)(B) of the Social Security Act (the Act) by adding the following sentence at the end: ''In establishing such rates, the Secretary shall provide for appropriate adjustments to increase each rate to reflect the demonstration rate (including the risk adjustment methodology associated with such rate) of the social health maintenance organization end-stage renal disease capitation demonstrations (established by section 2355 of the Deficit Reduction Act of 1984, as amended by section 13567(b) of the Omnibus Budget Reconciliation Act of 1996), and shall compute such rates by taking into account such factors as renal treatment modality, age, and the underlying cause of the end-stage renal disease.'' This amendment applies to payments for months beginning with January 2002.

Currently, Medicare+Choice (M+C) end-stage renal disease (ESRD) capitation payments are based on State-level rates that are not risk-adjusted. M+C ESRD base payment rates are based on the current M+C payment methodology, which builds on a base year (1997) amount representing 95 percent of projected State average fee-for-service costs, as determined at the time. M+C ESRD rates include the costs of beneficiaries with Medicare as Secondary Payer (MSP) and the costs of beneficiaries who have functioning grafts 3 years or less from date of transplant. Note that for the purpose of M+C payment, ''ESRD beneficiaries'' includes beneficiaries with ESRD, whether entitled to Medicare because of ESRD, disability, or age.

On May 25, 2001, the Secretary announced that he will work closely with all interested parties to explore and implement a risk adjustment process for M+C payments that balances accuracy and administrative burden. The ESRD payment methodology falls under this review of our current risk adjustment system. For this reason, we will implement the age and sex adjusters for calendar year (CY) 2002, while continuing to review other options for subsequent years, including those suggested by the commenters on the proposed notice.

A. ESRD Managed Care Demonstration Project

Beneficiaries with ESRD are the only group eligible for benefits under Parts A and B who are prohibited from enrolling in M+C organizations, although a beneficiary who develops ESRD after enrolling with an organization that offers an M+C plan may remain enrolled with the organization under an M+C plan. In 1993, the Congress required the Secretary to conduct an ESRD Managed Care Demonstration Project to assess whether it is feasible to allow enrollment in managed care for Medicare ESRD patients of all ages and to test risk-adjusted capitation for ESRD beneficiaries. As of December 2000, there were two such Demonstration sites, one in California with approximately 1,200 enrollees and a second in Florida with approximately 600 enrollees.

The ESRD Demonstration introduced 100 percent risk-adjustment into ESRD capitation payments. We calculated separate monthly capitation rates by treatment modality (dialysis, transplant, or functioning graft), and then adjusted the dialysis and functioning graft rates for age (0–19, 20–64, or 65+ years old) and original cause of renal failure (diabetes or other cause).

Further, the Demonstration tested whether offering additional benefits not covered by Medicare enhanced effective treatment of this population. The statute mandated that we pay ESRD Demonstration sites 100 percent of estimated per capita fee-for-service expenditures in that State, rather than the 95 percent of this same amount that was paid to managed care plans outside the Demonstration. To justify the extra 5 percent, ESRD Demonstration sites agreed to provide additional benefits, for example, nutritional supplements.

Finally, the Demonstration did not allow ESRD patients with MSP status to enroll in the sites. Therefore, we excluded fee-for-service beneficiaries with MSP from calculation of the base payment rates. Excluding MSP beneficiaries increased the Demonstration rates about 20 percent over rates paid outside the Demonstration.

B. ESRD Demonstration Experience With the Capitated Payment System

Preliminary assessments revealed that the administrative demands of implementing the risk adjustment methodology employed in the ESRD Demonstration were substantial and complex. CMS and the Demonstration sites experienced difficulty with ensuring accurate and timely collection of data on treatment modality; data problems also occurred with the original cause adjuster. In large part, this was because we had to rely on nonbilling documents to determine payment status. For example, the documentation of a transplant involves a detailed medical form that must travel from transplant center to organ transplant network to us. Often we did not receive these forms timely. Working with the earlier years of the Demonstration sites, we had to create complex processes for retroactive adjustments and reconciliations because of delays in receipt of the appropriate documentation.

This preliminary assessment is based on our analysis of issues that arose during the ESRD Demonstration. The final evaluation of the ESRD Demonstration is forthcoming. Meanwhile, we are pursuing further improvements to the payment system for ESRD beneficiaries enrolled in managed care. The ESRD Demonstration has received an extension until January 1, 2002. Under the terms of the extension granted to the two sites, an unadjusted capitation rate is paid (in contrast to the demonstration, for which rates were risk-adjusted). The extensions are scheduled to terminate December 31, 2001. At that time, the residual demonstration enrollees will be transitioned into the organizations' M+C plans and the extension methodology will be superseded by implementation of the new M+C ESRD payment methodology set forth in this notice.

II. Provisions of the Proposed Notice

On May 1, 2001, we published a proposed notice in the **Federal Register** (66 FR 21770) that proposed to establish a new payment methodology, effective January 2002, for beneficiaries with ESRD who are enrolled in M+C plans. The discussion below summarizes the provisions of that notice.

A. Calculation of State-Level Per Capita ESRD Rates at 100 Percent of State Fee-for-Service Costs

The BIPA requires that M+C ESRD rates be increased to reflect the Demonstration rates. We discussed our approach to reflecting the Demonstration base rate calculations in section II.A. of the May 1, 2001 proposed notice. To summarize, we proposed to increase the 1997 base rate produced by the pre-BIPA M+C ESRD payment methodology by approximately 1 percent to get to 100 percent of actual fee-for-service costs for 1997, thus fulfilling the BIPA mandate that new ESRD rates be increased to reflect the Demonstration rates, which are based on a 100 percent standard.

• Our analysis of the 1997 rates reveals that the national per capita rate promulgated in 1997 (based on September 1996 calculations) is about 4.1 percent higher than our current best estimate of the actual 1997 fee-for-service costs on which the rates are based.

• Under the M+C methodology set forth in the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA), the original 1997 rates were the basis for all future rates, with no provision for correcting over or under estimates for that year. This means that, on average, in 1997, we paid managed care organizations an amount representing about 99 percent of the actual Medicare Average Annual Per Capita Cost (AAPCC) for 1997, rather than the assumed 95 percent of the AAPCC.

To pay M+C organizations 100 percent of estimated State per capita ESRD fee-for-service costs for 1997, therefore, we proposed to increase the 1997 rates by approximately 1 percent.

See Section II.A. of the proposed notice HCFA–1182–PN (66 FR 21770) for an in-depth discussion of the rationale behind our proposed approach to paying 100 percent of State fee-for-service costs in a base year.

B. Risk Adjustment of the Base Payment Rates by Age and Sex

As noted above, section 605 of BIPA requires that the increase in ESRD rates to reflect Demonstration rates include the risk adjustment methodology associated with those rates. The methodology in place at the time the BIPA was enacted is set forth above in section I.A. Also see Section II.B. of the proposed notice for discussion of our approach to risk adjustment of M+C ESRD payments.

We proposed to adjust M+C ESRD rates only for age and sex. We believe that this reflects the most significant effects of the ESRD Demonstration methodology in effect at the time of the BIPA. Our reasons are presented below. While the Demonstration methodology included several components, the bulk of the effect of risk adjustment is attributable to adjustment for age. To increase the power of the age adjustment compared to the ESRD Demonstration age adjustment, we are changing from a 3-category age classification to the 10-category classification currently used in the M+C payment methodology.

We decided not to create separate rates for treatment modality or adjust for original cause of kidney failure for several reasons. In the proposed notice, we indicated that when we implement the comprehensive risk adjustment model (adding ambulatory and outpatient diagnoses to the existing hospital-diagnosis system), we would incorporate M+C ESRD enrollees into the single risk-adjusted payment system. This allows us to capture co-morbidity information in addition to demographic information and basic disease markers for ESRD beneficiaries.

In addition, research indicates that increased age is the single best correlate of ESRD mortality. The ESRD population enrolled in managed care is on average older than the ESRD fee-for-service population (see table below). (This is due to the current restrictions on ESRD enrollment in M+C organizations.) Our research comparing the 1998 Medicare HMO ESRD population with the fee-for-service population reveals the following contrasts (Eggers 2000).

Age	Percent of ESRD HMO population	Percent of ESRD fee-for-service population
Age 75+	28	15
65–74	41	22
45–64	24	39
0–44	7	24

We reviewed other evidence before selecting an interim risk adjustment methodology based on age and sex, including the following:

• Eggers et al. (2001) found that when taking age into account, M+C organizations were transplanting at the same rates as fee-for-service organizations in 1998.

• A detailed study of capitation models for ESRD (The Lewin Group and URREA 2000) showed that age is a much more important factor predicting 1996 fee-for-service spending for within-year transplant patients, functioning graft patients, and pediatric dialysis patients than it is for adult hemodialysis patients. The study noted, however, that ESRD patients enrolled in Medicare HMOs with Medicare as primary payer are *not* included in the sample of patients analyzed, so we do not know whether the study findings are accurate for the M+C ESRD population, which is on average older than the fee-for-service ESRD population.

Taking into consideration the current enrollment restrictions in the M+C program and the resulting age distribution of M+C ESRD enrollees, we concluded that adjusting for age and sex and using a more detailed age categorization obviates the need to include treatment modality and original cause as factors in this interim methodology. We also stated in the proposed notice that a change in the law to allow ESRD beneficiaries of all ages to enroll in M+C plans would result in moderation of the average payment increases expected from the proposed methodology. Preliminary findings from the ESRD Demonstration, which allowed ESRD beneficiaries of all ages to enroll, indicate that the age distributions at the Demonstration sites were very similar to the ESRD age distribution in fee-for-service Medicare. Thus, under open enrollment, we would expect a shift in the age distribution of the M+C ESRD population toward younger enrollees.

The proposed notice also stated that, although the ESRD Managed Care Demonstration did not allow beneficiaries with MSP to enroll, we are unable to exclude from the M+C program any beneficiaries with MSP who develop ESRD. Therefore, these ESRD beneficiaries with MSP will be

included in the program and payment rates. Due to data limitations, we noted that we did not expect to make separate payment adjustments.

III. Analysis of and Responses to Public Comments on the May 1, 2001, Proposed Notice

We received 6 items of correspondence containing a variety of comments on the proposed ESRD payment methodology. Commenters included managed care organizations and other industry representatives, representatives of physicians and other health care professionals, a research organization, and beneficiary advocacy groups. The comments concerned both parts of the proposed methodology: the 1 percent increase in the 1997 base year rate and the risk adjusters that we proposed.

Comment: Some commenters objected to our proposal to increase the ESRD State base rates by only 1 percent.

In particular, they recommended that, to increase the base payment rates from 95 percent to 100 percent of the average adjusted per capita cost (AAPCC), CMS should increase the 1997 State per capita M+C ESRD rates by 5.26 percent (100/95 = 1.0526).

Response: We have reviewed the arguments supporting the 1 percent increase, which were set forth in the proposed notice and summarized above, and the commenters' argument in favor of a 5.26 percent increase. We also have reviewed the terms and conditions of the ESRD Demonstration. As provided in section 2355 of the Deficit Reduction Act of 1984, as amended by section 13567(b) of the Omnibus Budget Reconciliation Act of 1996, which mandated the SHMO Demonstration, payment was to be based on 100 percent of estimated per capita fee-for-service expenditures in Demonstration States, rather than the 95 percent of this same amount that was paid to managed care plans outside the Demonstration. To justify the extra 5 percent, ESRD Demonstration sites were required to provide additional non-Medicare covered benefits especially needed by the ESRD population, for example, nutritional supplements. The ESRD Demonstration received an extension until January 1, 2002. Under the terms of the extension, the two sites must continue to offer the additional benefits.

While the approach we presented in our proposed notice would reflect the original Demonstration rates in that it would pay 100 percent of our best estimate of fee-for-service costs, the approach recommended by the commenters would come closer to paying the base rate amounts actually paid under the ESRD Demonstration. The BIPA statute requires that ''appropriate'' adjustments be made to ''reflect'' the demonstration *rates,* not necessarily that all M+C organizations be paid the *amounts* paid under the ESRD Demonstration. Even if one were to accept the commenters' premise that payment should be closer to the amounts paid under the Demonstration (rather than our proposal, which more accurately reflects the payment standard provided for in the SHMO demonstration statute), we have determined that a full 5.26 percent increase in the base rates would not be appropriate. This is because the additional benefits required under the Demonstration cannot be required of M+C plans outside this Demonstration, and at least some portion of the additional 5.26 percent paid under the ESRD Demonstration can be attributable to these additional benefits.

Accordingly, we have decided that a midpoint between our proposed 1 percent increase and the commenters' suggested 5.26 percent increase in the base rates is the most appropriate proxy for 100 percent of estimated per capita fee-for-service expenditures for ESRD beneficiaries, and thus the most appropriate way to ''reflect'' the Demonstration rates. Therefore, CMS will increase the ESRD base rates by 3 percent. This increase reflects the Demonstration methodology, and acknowledges that CMS cannot require M+C plans outside this Demonstration to offer the additional benefits that we required in the Demonstration in exchange for capitation rates set at 100 percent of fee-for-service costs. The 3 percent increase also represents the middle ground between two reasonable interpretations of the statute.

Comment: Although commenters were pleased that CMS will introduce age and sex risk adjusters into M+C ESRD payments beginning in 2002, all expressed concern that CMS was not using additional adjusters in order to pay more accurately for high severity cases. In particular, all commenters suggested that we add some combination of the following adjusters: whether diabetes is original cause of ESRD, treatment status (dialysis, transplant, post-transplant functioning graft), and Medicare Secondary Payer (MSP) status.

Response: On May 25, 2001, the Secretary announced that he will work closely with all interested parties to explore and implement a risk adjustment process for M+C payments that balances accuracy and administrative burden. The ESRD payment methodology falls under this review of our current risk adjustment system. For this reason, we will implement the age and sex adjusters for calendar year (CY) 2002, while continuing to review other options for subsequent years, including those suggested by the commenters on the proposed notice. We recognize that MSP status is an issue, and we plan to explore options within our payment system. We also plan to explore the feasibility of payment areas for ESRD enrollees that are smaller than States.

Meanwhile, the age and sex factors for ESRD beneficiaries enrolled in M+C plans that were developed by CMS's OACT and published in the proposed notice will be used in making payments for ESRD beneficiaries starting in January 1, 2002.

IV. Provisions of the Final Notice

We increased the 1997 M+C ESRD State rates by 3.00 percent, and then updated the rates to CY 2002 using the BBA methodology, which resulted in the minimum percentage increase each subsequent year. We will adjust payments with age and sex factors.

Below are two tables presenting the State M+C ESRD rates for CY 2002 and the age/sex factors for calculating M+C ESRD enrollee payments. In the first table, Average DF refers to Average Demographic Factor. Under the provisions of this notice, the Average DFs are average age/sex factors per State for Part A and Part B. ''New 2002 rates'' refer to the ESRD rates that follow from the BIPA mandate and will be implemented January 1, 2002. They are statewide rates standardized by State average DFs (average age and sex factors) and increased by 3.00 percent.

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CY 2002 Medicare+Choice End Stage Renal Disease State Rates

State	Average DF* Part A	Average DF Part B	New 2002 Rates** Part A	New 2002 Rates Part B
ALABAMA	1.0150	1.0027	$ 1,567.49	$ 2,220.99
ALASKA	0.9588	0.9733	$ 1,577.52	$ 2,175.23
ARIZONA	1.0105	0.9998	$ 1,711.35	$ 2,421.92
ARKANSAS	1.0070	0.9969	$ 1,510.80	$ 2,135.97
CALIFORNIA	1.0089	0.9991	$ 1,924.20	$ 2,721.24
COLORADO	0.9861	0.9844	$ 1,650.55	$ 2,314.51
CONNECTICUT	1.0763	1.0381	$ 1,835.45	$ 2,665.25
DELAWARE	1.0269	1.0092	$ 1,815.53	$ 2,586.94
DIST. OF COL.	1.0150	1.0014	$ 2,127.92	$ 3,021.13
FLORIDA	1.0419	1.0159	$ 1,619.19	$ 2,325.01
GEORGIA	0.9992	0.9926	$ 1,658.18	$ 2,336.85
HAWAII	1.0040	0.9967	$ 1,746.72	$ 2,463.57
IDAHO	0.9911	0.9890	$ 1,310.17	$ 1,837.02
ILLINOIS	1.0431	1.0207	$ 1,598.83	$ 2,287.66
INDIANA	1.0524	1.0223	$ 1,456.72	$ 2,099.01
IOWA	1.0627	1.0267	$ 1,357.23	$ 1,966.13
KANSAS	1.0467	1.0184	$ 1,550.87	$ 2,231.48
KENTUCKY	1.0197	1.0041	$ 1,855.46	$ 2,638.87
LOUISIANA	1.0077	0.9968	$ 2,003.87	$ 2,837.15
MAINE	1.0787	1.0372	$ 1,366.82	$ 1,989.61
MARYLAND	1.0263	1.0094	$ 1,892.04	$ 2,693.90
MASSACHUSETTS	1.0895	1.0441	$ 1,809.44	$ 2,644.54
MICHIGAN	1.0523	1.0233	$ 1,569.55	$ 2,259.70
MINNESOTA	1.0787	1.0382	$ 1,556.24	$ 2,263.98
MISSISSIPPI	1.0038	0.9942	$ 1,659.35	$ 2,345.58
MISSOURI	1.0394	1.0155	$ 1,605.04	$ 2,300.05
MONTANA	1.0272	1.0058	$ 1,164.07	$ 1,662.95
NEBRASKA	1.0293	1.0074	$ 1,322.36	$ 1,890.58
NEVADA	0.9661	0.9785	$ 1,676.54	$ 2,317.48
NEW HAMPSHIRE	1.0514	1.0249	$ 1,464.79	$ 2,103.47
NEW JERSEY	1.0523	1.0227	$ 1,821.60	$ 2,624.97
NEW MEXICO	1.0061	0.9997	$ 1,534.39	$ 2,161.52
NEW YORK	1.0294	1.0108	$ 1,983.50	$ 2,829.18
N. CAROLINA	1.0160	1.0019	$ 1,632.70	$ 2,317.94
N. DAKOTA	1.0544	1.0266	$ 1,249.01	$ 1,794.87
OHIO	1.0499	1.0236	$ 1,622.43	$ 2,329.83
OKLAHOMA	1.0170	1.0052	$ 1,451.87	$ 2,056.01
OREGON	0.9826	0.9830	$ 1,664.95	$ 2,329.90
PENNSYLVANIA	1.0655	1.0317	$ 1,884.50	$ 2,725.94
PUERTO RICO	0.9669	0.9762	$ 1,416.61	$ 1,963.42
RHODE ISLAND	1.0746	1.0334	$ 1,674.47	$ 2,438.13

S. CAROLINA	0.9998	0.9933	$ 1,612.85	$ 2,272.56
S. DAKOTA	1.0528	1.0229	$ 1,443.34	$ 2,079.32
TENNESSEE	1.0143	1.0011	$ 1,591.10	$ 2,256.85
TEXAS	1.0028	0.9960	$ 1,799.30	$ 2,536.74
UTAH	0.9577	0.9722	$ 1,211.69	$ 1,669.44
VERMONT	1.0899	1.0444	$ 1,498.68	$ 2,189.63
VIRGIN ISLANDS	0.9634	0.9793	$ 1,300.15	$ 1,789.39
VIRGINIA	1.0254	1.0091	$ 1,595.68	$ 2,269.81
WASHINGTON	1.0018	0.9945	$ 1,640.29	$ 2,313.16
W. VIRGINIA	1.0549	1.0236	$ 1,551.75	$ 2,238.85
WISCONSIN	1.0707	1.0350	$ 1,304.62	$ 1,888.53
WYOMING	0.9928	0.9902	$ 1,299.01	$ 1,822.18
GUAM	0.8000	0.9000	$ 1,616.53	$ 2,010.38

* Average DF refers to Average Demographic Factor
** "New 2002 Rates" follow from the BIPA mandate and are State-wide, standardized by State Average DFs (average age and sex factors), and increased by 3.00 percent.

BILLING CODE 4120–01–C

AGE/SEX DEMOGRAPHIC FACTORS FOR M+C ESRD ENROLLEES

Age	Part A		Part B	
	Male	Female	Male	Female
0–34	.55	.70	.70	.75
35–44	.65	.70	.80	.80
45–54	.70	.85	.85	.90
55–59	.80	.95	.90	1.00
60–64	.90	1.10	.90	1.10
65–69	1.15	1.35	1.10	1.20
70–74	1.25	1.45	1.15	1.25
75–79	1.30	1.55	1.20	1.25
80–84	1.40	1.60	1.20	1.25
85+	1.45	1.60	1.20	1.25

To calculate the payment for a given ESRD enrollee, multiply the appropriate age/sex factors by the standardized statewide M+C ESRD payment rates in the table. (Prior to January 2002, there are no adjustments for age and sex for M+C ESRD beneficiaries.)

Given current enrollment restrictions, we estimate that, under this methodology, the age- and sex-adjusted average ESRD payment per beneficiary will result in a significant increase in payments to M+C organizations for their ESRD enrollees.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

We have determined that this final notice is not a major rule with economically significant effects. There are approximately 18,000 ESRD beneficiaries enrolled in M+C plans. The additional cash expenditures for these M+C ESRD beneficiaries under this BIPA provision are estimated to be: $35 million in Fiscal Year (FY) 2002; $55 million in FY 2003; $55 million in FY 2004; $60 million in FY 2005; and $65 million in FY 2006. These estimates assume continuation of the current restrictions on enrollment in the M+C program for ESRD beneficiaries. These estimates include the impact of adjusting for age and sex and the impact of raising the ESRD base rates by 3.00 percent. Since this final notice results in increases in total expenditures of less than $100 million per year, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze the economic impact on small entities, and if an agency finds that a regulation imposes a significant burden on a substantial number of small entities, it must explore options for reducing the burden. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and

government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.5 million or less annually. For purposes of the RFA, most managed care organizations are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final notice will have no consequential effect on State, local, or tribal governments, and the private sector cost of this rule falls below these thresholds as well.

We have reviewed this final notice under the threshold criteria of E.O. 13132, Federalism. We have determined that this final notice will not significantly affect the rights, roles, and responsibilities of the States.

We have examined the economic impact of this notice on M+C organizations and find that the overall impact is positive. However, because the number of ESRD patients enrolled in M+C organizations represents a very small fraction of M+C organizations' annual receipts, and because a small number of M+C organizations qualify as small entities under the RFA, the Secretary is certifying that this notice will not have a significant impact on a substantial number of small entities. To our knowledge, no small rural hospitals will be affected by this notice, so the Secretary is also certifying that this notice will not have a significant impact on a substantial number of small rural hospitals.

In accordance with the provisions of E.O. 12866, this final notice was reviewed by OMB.

Works Cited

Eggers, Paul W., Diane L. Frankenfield, Joel W. Greer, William McClellan, William F. Owen, Jr., and Michael V. Rocco, ''Comparison of Mortality and Intermediate Outcomes between Dialysis Patients Enrolled in HMO and Fee for Service,'' February 2001. Under review at the American Journal of Kidney Disease.

Eggers, Paul. ''Outcome of ESRD Patients in HMOs.'' RPA/REF 2000 Annual Meeting. Washington D.C. March 25–27, 2000.

The Lewin Group and University Renal Research and Education Association (URREA). ''Capitation Models for ESRD: Methodology and Results.'' Prepared for Renal Physicians Association, American Society of Nephrology, American Society of Transplant Physicians, American Society for Pediatric Nephrology, and Amgen. January 7, 2000.

Section 1853(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)(B))

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

Dated: July 30, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 16, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–24494 Filed 9–28–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0384]

Preparation for Global Harmonization Task Force Conference in Barcelona, Spain, Including a Discussion of Guidance Proposed for Comment and Currently Under Development and Possibilities for New Topics; Public Meeting; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the public meeting for the Global Harmonization Task Force Conference in Barcelona, Spain scheduled for October 1, 2001. The meeting was announced in the **Federal Register** of September 13, 2001 (66 FR 47676). It will be rescheduled at a later date.

FOR FURTHER INFORMATION CONTACT: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

Dated: September 25, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24527 Filed 9–26–01; 3:57 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0370]

Preparation for ICH Meetings in Brussels, Belgium, Including Progress on Implementing of the Common Technical Document; Public Meeting; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the public meeting for the ICH meetings in Brussels, Belgium scheduled for October 5, 2001. The public meeting was announced in the **Federal Register** of September 7, 2001 (66 FR 46801). It will be rescheduled at a later date.

FOR FURTHER INFORMATION CONTACT: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

Dated: September 25, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24528 Filed 9–26–01; 3:57 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting; Cancellation

In **Federal Register** Document 01–23611 appearing on page 48691 in the issue for Friday, September 21, 2001, the meeting scheduled for October 11–14, 2001, has been cancelled.