THE ERISA INDUSTRY COMMITTEE

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Advocating the Benefit and Compensation Interests of America's Major Employers

October 4, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule Regarding Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)

Dear Administrator McClellan:

The ERISA Industry Committee (ERIC) respectfully submits these comments in response to proposed regulation "Medicare Program; Medicare Prescription Drug Benefit" published in the *Federal Register* on August 3, 2004. ERIC developed these comments based on input from member companies participating on our ERIC Medicare Implementation Task Force and through an ERIC member survey.

We commend the Centers for Medicare and Medicaid Services (CMS) for timely issuing proposed Medicare regulations and its continued outreach to the employer community to create a sound regulatory framework for the nation's most important health system for retirees. These comments are in addition to and supplement ERIC's request for guidance submission to the CMS dated May 27, 2004. We also reserve the right to supplement these comments as work on the regulations continues.

We look forward to working with you and your staff to further discuss our suggestions and recommendations. If you would like to schedule a meeting or conference call to discuss these comments please contact Edwina Rogers, ERIC's Vice President, Health Policy at 202-789-1400.

I. INTRODUCTION

A. The ERISA Industry Committee

The ERISA Industry Committee is a nonprofit association committed to the advancement of the employee retirement, health and other benefit plans of America's largest employers. ERIC's members provide comprehensive retirement, health care

coverage, and other economic security benefits directly to some 25 million active and retired workers and their families. ERIC has strong interests in proposals affecting its members' ability to deliver those benefits, their cost and effectiveness, and the role of those benefits in the American economy.

B. Current Membership Retiree Medical Benefits

ERIC Member Survey Results *- ERIC conducted a survey on September 8, 2004 to gather additional information to respond to numerous specific questions presented in the proposed Medicare regulations. All survey information will be titled "**ERIC Member Survey Results**" and the text identified by italic typeface and only represents the opinions of member companies that completed the survey. Member companies that responded to the survey stated that 71% offer retiree medical benefits to current and some future retirees while 29% offer current retirees and current actives retiree medical benefits. The retiree drug plans vary from 100% of the premiums paid by the plan sponsor to access only plans.*

C. Available Employer Options and Dropping of Coverage

Issue for Discussion

In its Discussion Paper dated August 19, 2004, CMS stated they are particularly interested in hearing what employers are likely to do under the various proposed options. CMS further stated, "[e]mployer-sponsored insurance has been an important source of drug coverage for many Medicare beneficiaries. However, for well over a decade, the availability of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. We believe that Medicare Part D, including the retiree drug subsidy and the other options it gives employers for providing enhanced drug coverage, will help to counteract this trend by increasing the financial support available to employers for retiree drug coverage."

The CMS Office of the Actuary (OACT) reports there is considerable uncertainty associated with how employers and unions will react to the new Medicare drug benefit. This uncertainty has been compounded by the lack of information available before the release of the proposed rules. The additional information CMS is seeking from employers and their advisors should help reduce the uncertainty and facilitate the preparation of specific estimates of the extent to which employers and unions will take each of the available options.

Also included in the August 19th CMS Discussion Paper was a request for comments on whether some retirees would have reduced drug costs if their employer ceases to provide retiree drug coverage. The CMS Discussion Paper went further to state "[t]his appears possible in some retiree plans because, although offered by an employer, the retirees pay most or the entire plan premium themselves. From the standpoint of their estimated drug payments, such retirees may be better off purchasing

a basic or an enhanced Medicare drug plan on their own instead of continuing to receive drug coverage through their employer plan."

ERIC Discussion

ERIC Member Survey Results *- When asked which employer option their company is most likely to select under the proposed Medicare regulations, 64% of the respondents selected the retiree drug subsidy, 7% selected the wrap around option, 7% will contract or directly sponsor a PDP or Medicare Advantage plan, while the remaining 21% have not decided as of this time.*

When asked if dropping coverage was available to a member company for some or all of its retirees 79% stated that this option is available while 21% are bound by collectively bargained agreements or other contractual or legal agreements to continue their plans. Finally, when asked if some or all of their retirees would have reduced drug coverage under the Medicare drug plan, 50% stated that none of their retirees would be better off under Part D, 28% stated that some of their classes would be better off under Part D, while the remaining 21% stated that they do not have enough information at this time to determine the answer.

II. TIMING ISSUES

Issue for Discussion

For plan year 2006, the Medicare regulations do not require notice of rates, regions and benefits for Part A and B until February 2005, with confirmation in April 2005. Part D Medicare coverage best estimates will be released around June 6, 2005. Benchmark bids, best and final offers and negotiations will be completed for open enrollment on November 15, 2005.

ERIC Recommendation

CMS should release additional guidance and the final regulations as quickly as possible on the employer related provisions, given the tight time frame that employers will face in 2005 regarding the design, pricing and communication of their 2006 plans. ERIC urges CMS to issue final regulations no later than December 31, 2004. In the interim, we encourage CMS to share any other information that they have available in order to minimize the uncertainty of what will be required of employers in 2005, including addressing such issues as the calculation of actuarial equivalence for employer group retiree plans. The timing issues affect both employers who plan to accept the subsidy as well as those who plan to wrap around Medicare Part D coverage. We respectfully request the opportunity to comment on any and all future guidance.

ERIC urges CMS to issue the final rule as early as possible after the close of the comment period but no later than December 31, 2004 to enable plan sponsors enough

time to meet CMS deadlines. We also urge CMS to issue guidance addressing areas critical to the timely implementation of options available to employers under the Medicare regulations. Some of the critical areas of concern include methodologies and actuarial assumptions for determining actuarial equivalence and the underlying values, the process for obtaining waivers, the allocation of employer and retiree dollars, and notice requirements regarding creditable coverage. Issuance of such informal guidance would be consistent with the practices of other regulatory agencies with authority over employer-sponsored benefit and compensation programs.

ERIC members typically begin planning their health plan changes a year in advance of the plan year in which those changes will take effect. Since knowing whether a plan's prescription drug coverage is actuarially equivalent to the Medicare standard benefit is now integral to this planning process, it is essential that plan sponsors have adequate notice of the actuarial value against which they are benchmarking their plans for each plan year, as well as the methods and processes to be used in determining actuarial equivalence. ERIC urges the Secretary to publish the projected value of the Medicare standard prescription drug benefit, and any new or revised methods and processes for determining actuarial equivalence, no later than April 1 of the year prior to the year for which the value, methods and processes will be used.

The timeframe proposed by CMS leaves inadequate time for employers to redesign health benefit plans to comply with the new rules and qualify for the subsidy or determine to choose one of the other options available to employers. In addition, the FASB Staff Position on Accounting for the Act (FSP 106-2) is effective for the first interim or annual period beginning after June 15, 2004 (third quarter 2004 for calendar year-end employers). Accordingly, employers need to consider how to account for the effect of the Medicare Modernization Act (MMA) - even before CMS issues final regulations. The timeframe proposed by CMS is, therefore, unrealistic.

A. Timing And PDPs

Issue for Discussion

Employers that want to contract with prescription drug plans (PDPs) to provide an enhanced drug benefit to their retirees need to make contracting decisions in advance of the September 2005 bid approval date. In fact, many employers will need to make this decision before the June 6, 2005 bid submission date.

ERIC Recommendation

ERIC encourages CMS to modify the timeline for the 2005 bidding to include earlier submissions and approval and to use its waiver authority to help resolve issues raised by potential PDP sponsors.

B. Must Apply for Subsidy by September 30, 2005

Issue for Discussion

A plan sponsor who wishes to receive the subsidy must apply annually no later than 90 days before the beginning of the year. For 2006, applications must be submitted by September 30, 2005. ERIC's comments on this approach follow, including the effects of the deadline, and whether a sponsor will know in which plan option a beneficiary has enrolled.

ERIC is concerned about the timing and the content of the application process for the employer subsidy. Most enrollment periods for employers on a calendar year are not completed by September 30th and there are even greater issues for plan sponsors who are not on a calendar year. Generally, the September 30th deadline is difficult to meet because of the requirement to include the attestation of actuarial equivalence and the data required to support the subsidy payment, including eligible retirees.

ERIC Recommendation

ERIC recommends that CMS provide greater flexibility so that an employer may submit the actuarial attestation by September 30 to establish the plan's eligibility for the subsidy and then allow other supporting data to be filed by December 31. ERIC suggests that CMS provide guidance on the actuarial equivalent threshold 60 days prior (minimum 30 days) to the application deadline. An employer may not know by September 30th the plan option a retiree chooses if they offer annual open enrollment. For example, the open enrollment period may end after September 30th and, for employers with union retirees, the collective bargaining process may not end until after September 30th.

Further, ERIC recommends that CMS provide an electronic application process that would also be updated electronically. In addition, ERIC strongly believes that the attestation of actuarial equivalence and the application for the subsidy should be disclosed exclusively to CMS and under no circumstances disclosed to third parties. The data and the application most likely will include proprietary information as well as be subject to privacy standards.

Under the MMA, the Department of Health and Human Services is not required to "approve" the actuarial attestation but does have discretion to challenge an attestation if it has reason to doubt its accuracy. The MMA does not authorize individuals or their representatives to challenge the attestation of actuarial equivalence. Disposition of such challenges could make implementation of the program unworkable and give rise to frivolous challenges. The application is required to be signed under penalty of perjury and is subject to the civil and criminal penalties of the False Claims Act, which should provide ample enforcement authority.

The proposed CMS rules imply that failing to meet the September 30 filing deadline would preclude an employer from receiving any subsidy payment for the following year, even if an application for the subsidy were subsequently filed. ERIC strongly recommends that employers be required to submit just the actuarial equivalence attestation by the September 30 deadline. Information captured during the open enrollment process, such as specific enrollment data, could be submitted between September 30 and December 31.

Additionally, ERIC recommends that employers unable to meet the initial filing deadline or choosing to file mid-year should be allowed to file after the deadline. If the application were received after September 30, no subsidy payment would be made until 90 days after the application was filed.

C. Treatment of Health Plans Not Operating on a Calendar Year Basis

Issue for Discussion

A number of employer-sponsored health plans do not operate on a calendar year basis (i.e., the plan year coincides with the plan sponsor's fiscal year). It would be extremely disruptive to such plans if they were required to make mid-year plan amendments to maintain their actuarial equivalence whenever the value of the Medicare standard benefit is revised.

ERIC Member Survey Results *- In the ERIC member survey, 36% of the respondents stated that their health plan does not operate on a calendar year.*

ERIC Recommendation

ERIC recommends that CMS develop reasonable methods of using projected design limits in the actuarial attestation and a requirement that an application be filed 90 days before the plan year. Employers that have plans with non-calendar plan years may not be able to complete plan design changes by September 30th and will be presented with additional challenges for actuarial equivalence determinations if contribution amounts are needed.

ERIC believes that the final regulations should recognize and make allowances for and provide the flexibility to maintain non-calendar year plans. This flexibility could allow latitude in the actuarial attestation of equivalence if the Part D plan design limits are not known at the time the attestation is made.

III. ACTUARIAL EQUIVALENCE ISSUES

Issue for Discussion

CMS has proposed a broad definition of "actuarial equivalance" to mean equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11. CMS plans to develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage.

The single most important area in the regulations that can either make or break the intent of the MMA is the method(s) for determining actuarial equivalence. Clearly the intent of the MMA was to provide incentives for employers to continue their existing coverage or even enhance their coverage for retirees. Preserving employers' ability to maintain their current plans, without requiring employers to renegotiate or change their plans in order to receive financial support is paramount in reaching this goal.

Any misstep by CMS in establishing the threshold will result in many retirees involuntarily losing the ability to choose their employers' coverage causing a severe retiree backlash against the MMA. In particular, this is a major problem for retirees whose employer has placed a cap on its financial contribution toward retiree healthcare. In today's environment, this is more the rule than the exception. In addition, the only real options remaining for many employers will be coordinating with Medicare (clearly not an attractive option financially or administratively) or handing over the responsibility of providing drug coverage for their retirees to Medicare. The risk to the MMA is great because once an employer eliminates retiree benefits - it is not likely the employer will ever reintroduce the benefit.

The CMS proposed regulations set forth three potential approaches for determining whether an employer's plan meets the definition of actuarial equivalence, one of which is the two-prong test. The first prong compares the gross value of the employer's benefit to the value of the Part D benefit. The second prong compares the net value of the benefit (subtracting the portion financed by retiree contributions from the gross value of the benefit) to the value of the Part D benefit. CMS has proposed several basis for this comparison.

ERIC Recommendation

ERIC recommends that CMS use the two-prong approach (gross test on plan design and net value test) as an appropriate structure to prevent an employer from receiving more than it contributed to a plan. When limited to the options proposed by CMS regarding the second prong of the two-prong approach, ERIC prefers (confirmed by our member survey) that CMS use the average value of the retiree drug subsidy (e.g., $611), but ERIC strongly also recommends that CMS allow flexibility in its approach and not stipulate a fixed-dollar value. The flexibility should address variations in costs based on geography, plan design, and utilization. ERIC recommends that a more flexible version

of the two-prong test be used because it is most consistent with our understanding of congressional intent.

Further, to make the two-prong approach work, CMS must set a reasonable threshold for employers to qualify for subsidies. This is especially true for employers, including several ERIC member companies, who have placed some form of cap on their contribution toward retiree health care. Without a reasonable threshold, employers will be forced to either walk away from sponsoring retiree coverage or, at best, change their current plans to coordinate with Medicare through an admittedly complex and potentially costly process.

ERIC strongly believes that the yearly average subsidy that is provided to each employer (estimated to be $611 per individual in 2006) is a proper threshold level. We do not believe, however, that the $900 amount that CMS valued the employer "wrap" coverage would be appropriate since it does not take into consideration the Part D premiums that would be required nor the additional administrative expenses. If these items are factored into the equation, the threshold should be set below $480. Finally, using a value of $1,200, which represents the average value an individual receives if he or she enrolls in Medicare Part D, is totally inappropriate. Employers and retirees are not receiving the full value of the drug benefit from Medicare and no beneficiary will be penalized since beneficiaries always have the option of disenrolling, without penalty (assuming the gross test is met for creditable coverage), from the employer's plan and enrolling in Medicare Part D. While we agree that Part D may be the appropriate plan for some retirees, it should remain each individual's choice to decide based upon their own unique needs and circumstances. We urge CMS to seriously consider establishing the net payment threshold at the expected average subsidy payment for each employer.

A. Appeals

Issue for Discussion

The appeals process CMS outlines in its proposed regulations do not give adequate protections for employers and do not incorporate the Administrative Procedures Act and administrative law judges. It is possible that some disputes could be over statutory interpretations and not merely data disagreements.

ERIC Recommendation

ERIC commends CMS on its decision to provide an opportunity for review of agency determinations in connection with the retiree prescription drug subsidy. To be sure, the issues embedded in an agency determination respecting eligibility of a plan sponsor for the subsidy, and calculation of the subsidy, are likely to be complicated, and in the initial years of the program there will be no precedent to guide the decision-makers. While ERIC supports a process that ensures expeditious processing and payment of subsidy amounts, there also is a need to balance expeditious payment with a fair and reasonable appeal process. ERIC requests that CMS consider whether to expand the

process to provide plan sponsors with an opportunity to develop a detailed record concerning disputes for which they request reconsideration. ERIC also requests CMS to consider, if it determines that no such opportunity needs to be provided, conceding that its factual determinations relating to a subsidy dispute be decided on a de novo basis upon judicial review. In addition, in connection with the proposed appeal provisions respecting reopening of an initial or reconsidered determination, ERIC requests that if an employer seeks to reopen a determination on its own, such a right should be unfettered as long as it is made within one year of final determination, and not a right that is granted merely at the discretion of the agency.

B. Ways to Encourage Employers to Increase the Benefit

Issue for Discussion

CMS also requested comments regarding setting the appropriate threshold to encourage employers to increase the generosity of their coverage. CMS stated, "adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher level."

ERIC Recommendation

ERIC does not believe the assertion that a lower threshold will discourage employers from increasing the generosity of their coverage and this statement does not reflect reality. Employers who provide retiree benefits do so voluntarily - to the extent they can - while maintaining their global competitiveness. If CMS sets the threshold too high, it will merely force employers toward one of the alternatives, including walking away from their support of retiree healthcare coverage. This is demonstrated by the decline in employer sponsored retiree healthcare coverage over time. Based on a 2004 Kaiser Survey of Employer-Sponsored Health Benefits, the percentage of large firms offering retiree health benefits has fallen from 66% in 1988 to 36% in 2004. Raising the threshold is tantamount to increasing costs, which is the reason for the precipitous decline in employer-sponsored coverage. Based on the above facts, we believe the logic for arguing the merits of higher thresholds is flawed and inconsistent with the legislative intent to encourage employers to sponsor voluntary retiree healthcare programs.

Clearly, Congress wanted to provide employers financial incentives to maintain coverage through the subsidy. However, placing arbitrary thresholds above the subsidy level, in effect, limits the duration of the subsidy intended by the legislation. While the legislative history supports the prevention of windfalls to employers, we find no basis for "raising the bar" above the minimum requirements necessary to prevent an employer windfall. Any provisions in the regulations that attempt to increase employers' financial support of retiree health coverage could have catastrophic implications for employer based retiree healthcare coverage.

In fact, there is no basis to conclude that a lower qualifying threshold will lower the level of employer support. There is no financial benefit to employers since the actual subsidy payment is defined by the statute and does not change regardless of the amount of the qualifying threshold. In addition, if employers have not already voluntarily chosen to lower their support and increase retiree contributions before the MMA, nothing has changed to make employers take this action under any scenario after MMA. There is no further incentive for employers to lower their support than already exists. If anything, an argument can be made to the opposite effect. By qualifying more employers for the subsidy, employers will have more financial resources than prior to the MMA and therefore have the ability and incentive to sustain or possibly increase their level of support. The only logical threshold that is consistent with legislative intent is to establish the level at the point necessary to prevent employer windfalls.

CMS's own data clearly indicates that establishing an inappropriate subsidy level threshold would be devastating to the intent of the MMA. The Office of the Actuary for CMS has demonstrated this fact in a memorandum dated September 2, 2004 to you. This memorandum showed that the number of employers being able to choose the subsidy decreases as the qualifying threshold increases. Based on the CMS actuary's estimates for employer subsidy payments versus the value of Medicare Part D for 2006, retirees and their dependents who are forced out of their employer's coverage will increase the federal government's spending by about $600 per individual annually.

C. Attestation of Actuarial Equivalence

Issue for Discussion

CMS asked whether the proposals related to attestation of actuarial equivalence provide sufficient protection for beneficiaries and whether these proposals are operationally feasible without creating an undue burden on sponsors. Attestation will be required on an annual basis to CMS and 90 days prior to material changes in coverage to CMS and beneficiaries. The attestation must be signed by an authorized representative of the plan sponsor, include a certification, signed under penalty of perjury, that indicates that the information contained in the attestation is true and accurate to the best of the attester's knowledge and which acknowledges that the information is being provided to obtain Federal funds.

ERIC Recommendation

ERIC agrees that with at least one exception the CMS proposals related to attestation of actuarial equivalence do provide sufficient protection for beneficiaries and are operationally feasible without creating an undue burden on sponsors. ERIC recommends that CMS not require the actuarial attestation of equivalency on an annual basis. The MMA states: "the sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require…" (Sec. 1860D-22a(2)(A)) We request that the CMS permit employers to submit annual updates to their applications to reflect any plan changes and new enrollment data. If no plan design changes occurred, we

request that CMS allow employers to attest that the design has remained the same and submit only new enrollment data. This process will allow CMS to verify eligibility and lessen the administrative burden on employers. Finally, it would be helpful if CMS provided standard language for the actuarial attestation statement.

D. Retiree Communications

Issue for Discussion

CMS asked for ideas on the most effective methods that companies have in conducting outreach to their company's retirees, as well as prospective venues for conducting outreach.

ERIC Recommendation

ERIC suggests that company mailings to retirees are the preferred communication method (confirmed by survey results). Additionally, ERIC believes that while there will always be a need to communicate via traditional mail and retiree organization meetings, retirees' use of technology, such as email and the web provides companies with additional resources and venues for communications. Given the scope and complexity of the Medicare legislation, it is safe to say that many different methods of communication will need to be utilized to help retirees navigate through the changes and understand what it means for them, including the potential for personalized communication.

IV. ACTUARIAL VALUE AND ALLOWABLE COSTS FOR CALCULATIONS

Issue for Discussion

According to section 1860D-11 of the Act, CMS will develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial value of prescription drug coverage. CMS fully expects to provide additional guidance in the future on these provisions. As noted in subpart F of the preamble, CMS will provide additional information in the future on the processes for determining actuarial value, including that of retiree prescription drug coverage. CMS anticipates specifying, as either recommended or required in further guidance, data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles.

ERIC Recommendation

As pointed out by numerous actuaries of ERIC member companies, actuarial valuation is a critical issue that needs to be resolved as soon as possible. Many other issues are secondary to getting this clarified because employers are left making decisions without

knowing the actual underlying numbers. The proposed regulations deferred this whole issue to future guidance. Guidance on actuarial valuation is much more critical to the valuation process than is finalizing the regulation that has already been proposed.

It is one thing to calculate the actuarial value of prescription drug coverage. It is quite another to apply an actuarial equivalence test. The proposed regulation focuses principally on the latter, assuming that the actuarial value is already known. Unfortunately, the proposed regulation does not address the determination of the actuarial value. For example, the "cap" issue is a part of this determination and, whether to use a fixed amount (e.g., $ 611) for the value of Part D versus modeling the Part D benefit for an employer's particular population and claims history is another part of this issue.

Any guidance CMS could provide in advance of the final rules regarding the methodologies and assumptions sponsors must use to determine the gross value of the benefit (whatever the threshold for the "second prong" of the test ends up being) would be extremely helpful and essential.

A. How to Handle Drug Rebates

Issue for Discussion

Regarding price concessions in the prescription drug industry, including the various forms these arrangements may take, as well as the pass through issues, CMS asked for comments on how rebates and other forms of remuneration can be most accurately applied to the cost data to efficiently satisfy the requirement that all rebates must be netted out of allowable retiree costs while minimizing the burden on sponsors.

ERIC Recommendation

There are both timing issues and methodology issues. We propose a two-phase settlement, with a preliminary (estimated) settlement right after the end of the year, followed by a final adjustment up to 12 months later. Rebates often are not settled until 9 to 12 months after the close of the year. The method for settlement after the end of the year should be based on actuarially sound estimates of rebates and discounts based on historic contracts or assumptions. ERIC recommends that CMS assist in developing reasonable time rules for settlement of rebates. On a final note, ERIC recommends CMS work to keep the rebate process flexible and minimize administrative burden.

B. How to Handle Dispensing Fees

Issue for Discussion

One of the critical elements in determining the "allowable retiree costs" on which the 28 percent subsidy will be based is "dispensing fees." The preamble to the proposed rules offers three alternative definitions of dispensing fees.

ERIC Member Survey Results *- ERIC members were asked to select one of the three alternative definitions of dispensing fees put forth by CMS in its proposed regulations. The results are as follows:*

- *43% preferred "the cost of transferring the drug from pharmacy to beneficiary";*
- *21% preferred "expenses of option 1 plus any expenses required to effectively administer the drug"; and*
- *36% selected "expenses of option 2 plus ongoing services needed to administer the drug, such as skilled nursing visits or pharmacy monitoring."*

ERIC Recommendation

CMS stated in the preamble that option 1 represents "the best reading of the statute, since it would limit dispensing fees to a transfer of the possession of the drug and would not include any fees associated with administering the drug." ERIC agrees with CMS that option 1 represents the best definition from an employer plan perspective. Generally under current practice, employer plans pay for dispensing fees that cover only what the pharmacy needs to do to dispense the medication and not other supplies and/or equipment and skilled nursing.

C. Request for Flexibility In Value Determinations

Issue for Discussion

As mentioned earlier, the proposed rules do not include the methodologies, assumptions and techniques for determining actuarial equivalence. CMS states that they will be provided in additional guidance.

ERIC Recommendation

ERIC recommends that in its guidance CMS provide flexibility in the use of methodologies and the selection of actuarial assumptions as long as the valuations follow generally accepted actuarial principles. We urge CMS to avoid using a fixed value test because the net value will depend upon the nature of the plan design and the expected utilization of benefits under the plan, which will necessarily vary from employer to employer. ERIC also requests that CMS provide the methodology and assumptions CMS actuaries will use in performing calculations.

V. DEFINITION OF HEALTH BENEFIT PLANS

Issue for Discussion

The MMA provides that the definition of a "group health plan" has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1) and includes church plans, governmental plans and other types of group health plans in addition to those sponsored by employers or unions. CMS has proposed using the approach adopted by the Department of Treasury in the context of administering COBRA for the definition of a plan when determining actuarial equivalence. It is not uncommon that a plan would include both a grandfathered group of retirees for whom the employer makes a substantial contribution and a non-grandfathered group with limited or no employer contributions. These situations would not necessarily be separate plans for COBRA purposes. It is possible that the employer plan could not meet actuarial equivalence for the grandfathered group with very generous employer contributions because of the averaging of the group with non-grandfathered retirees in the same plan.

ERIC Recommendation

ERIC believes a more flexible approach would be to retain the COBRA definition and adapt it to the complex world of retiree drug benefits by dropping the separate operational requirement and allowing for reasonable classifications based on the level of employer contributions and other factors. It is essential that employers have the flexibility to distinguish among groups of retirees with different benefit arrangements. Employers need the flexibility to define a plan in a manner that distinguishes between groups of retirees by simply amending the plan documents. In addition, CMS should not require a separate filing other than the attestation and actuarial equivalence to satisfy any documentation requirement for purposes of defining a plan.

VI. PLANS WITH INTEGRATED DRUG AND MEDICAL BENEFITS, CAPS AND ALLOCATION OF EMPLOYER CONTRIBUTIONS TOWARD SUBSIDY PAYMENT ELIGIBILITY

Issue for Discussion

Many ERIC members provide retiree health coverage that does not impose separate deductibles, out-of-pocket limits, premiums or other cost-sharing features on prescription drugs. Similarly, employers use various methods of funding the coverage they are providing (e.g., from cash on a PAYG basis or from an employer-funded VEBA trust.) There are compelling health policy reasons for doing so, and the processes and methods for determining actuarial equivalence should not dictate funding and financing decisions or plan design by effectively requiring employers to adopt separate deductibles, out-of-pocket limits, premium contributions or other cost-sharing for prescription drugs in order to meet the actuarial equivalence standard.

CMS staff has informally suggested that while there is a statutory test for drug plans (i.e., actuarial equivalence), there is no comparable specific statutory test for integrated plans. Thus, the statute would appear to leave room for a flexible approach as to how retiree cost-sharing (i.e., premium contributions, deductibles, out-of-pocket limits, caps, etc.) is allocated between drug and non-drug coverage within an integrated plan.

ERIC Recommendation

ERIC urges CMS to clearly state its policy on the degree to which CMS will allow plan sponsors latitude to apportion their premium subsidy between prescription drug benefits and medical benefits in integrated plans. This matter will be an important factor for many employers (especially those with caps) who are trying to determine if their plans can be considered actuarially equivalent.

Based upon the information received from the Employer CMS "open house" conference calls and other written material, it appears to be the employer's choice on how it allocates its retiree caps for purposes of qualifying for the MMA employer subsidy.

ERIC strongly agrees with this position, but this interpretation should be explicitly stated in the regulations to assure that employers can design their benefit plans with confidence of being in compliance with the law and to clarify the accounting options available to employers.

VII. Employer Group Waivers

Issue for Discussion

The waiver authority is intended to provide prescription drug plans an opportunity, similar to the opportunity afforded Medicare Advantage organizations, to furnish Part D benefits to participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations in the most efficient and effective manner possible. In the preamble, CMS invites comment on the process they should propose for authorizing additional waivers that prescription drug plan sponsors can request. CMS also asked for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, should not allow. The preamble also discussed waivers that CMS would not permit (e.g., waivers that would provide for a premium amount for employees/retirees of the employer sponsoring the plan that is different than the premium charged to individuals enrolled in the same PDP plan, and waivers that directly increase Medicare spending.)

ERIC Recommendation

ERIC recommends that CMS pursue an employer waiver process that maximizes flexibility for an employer to accomplish an appropriate employer –sponsored approach. Further, we suggest that CMS issue non-regulatory guidance addressing the employer waiver process before December 31, 2004. CMS should strongly consider

developing standard forms and instructions to be used by employers seeking waivers. Finally, we recommend that CMS create a dedicated office to work with employers interested in receiving waivers.

VIII. TRUE OUT-OF-POCKET EXPENSES (TrOOP) FOR PART D WRAP AROUND

Issue for Discussion

It is of great importance to establish clear responsibilities for TrOOP tracking and calculation processes in regulation in order to ensure that qualified beneficiaries receive appropriate coverage once they have met the out-of-pocket cost limit. CMS is considering the following options: 1) PDPs and MA-PD plans would be solely responsible for tracking TrOOP costs; and 2) CMS would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. CMS is requesting comments concerning the development of this system.

ERIC Recommendation

TrOOP tracking will be a cost issue for employers even if the responsibility rests with the PDPs or Medicare Advantage PDs. Coordinating benefits between unrelated PDPs and secondary benefit managers will be extremely cumbersome without a central data clearinghouse, and the PDPs will pass along the resulting additional administrative costs. CMS has said they "may" fund the development and implementation of a system to assist with coordination of benefits (COB) "if and when it is determined that our development of the system is the appropriate option."

ERIC encourages CMS to fund the development and implementation of a TrOOP facilitation contractor to act as a single source to receive data from primary and secondary payers as soon as possible. ERIC requests the CMS to establish a central clearinghouse entity for coordination of TrOOP much like it does for Medicare Part A and B.

A. Coordination of Benefits with Another Plan and Possible User Fees

Issue for Discussion

CMS may impose user fees for the transmittal of information necessary for benefit coordination related to third party reimbursement of Part D enrollees' costs for covered Part D drugs. By July 1, 2005, CMS must establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers including Medicaid programs, group health plans, the FEHBP, Military coverage and other coverage we may specify at a later date.

ERIC Recommendation

Even though the MMA provides CMS with the ability to charge user fees for coordination, we respectfully ask that CMS not exercise this authority. Employers are already financially disadvantaged compared to a beneficiary enrolling as an individual. It is unwise to increase employer cost any further as it will have a potential negative affect on the number of employers that choose to "walk away" from their existing levels of coverage.

B. Treatment of FSAs, HSAs, HRAs, and MSAs for TrOOP Purposes

Issue for Discussion

In its proposed regulations CMS requested comments regarding the treatment of health savings accounts (HSAs) vis-à-vis the definition of "group health plan," "insurance or otherwise" and "third party payment arrangements." CMS stated that its strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore to allow HSAs contributions to count toward incurred costs, since CMS sees these funds as essentially analogous to a beneficiary's bank account. CMS also seeks comments on how to treat flexible spending accounts (FSAs), health reimbursement accounts (HRAs), and medical savings accounts (MSAs), relative to the CMS definitions of group health plan, insurance or otherwise, and third party payment arrangements.

ERIC Member Survey Results *- CMS is inclined to treat any payments from HSAs as part of the Part D participant's incurred costs, apparently regardless of how the HSAs were originally funded. CMS also seeks comments on the TrOOP treatment of prescription drug payments from flexible spending accounts (FSA), health reimbursement accounts (HRAs) and medical savings accounts (MSA) (which can be part of a Medicare Advantage plan). The ERIC members survey results are as follows:*

- *64% chose "payments from HSAs, FSAs, HRAs and MSAs should count toward the TrOOP;*
- *14% chose "payments from HSAs, FSAs, HRAs, and MSAs should not count toward the TrOOP; and*
- *21% were undecided.*

ERIC Recommendation

ERIC recommends that CMS determine in its final regulations that FSAs, HSAs, HRAs, and MSAs, are not treated by CMS as group health plans and that all funds disbursed by retirees from these accounts are to be treated as incurred beneficiary costs for purposes of TrOOP, as long as these funds are broadly available for a wide range of medical services and treatments, and not limited to prescription drugs.

IX. CREDITABLE COVERAGE, NOTICES AND LATE PENALTIES

Issue for Discussion (Timely Notices and Notice of Change)

CMS proposes to require sponsors of group health plans to determine the actuarial equivalence of each group health plan to the standard if, on average, the actuarial value of enrollee drug coverage under the plan as a whole is at least equal to the actuarial value of standard prescription drug coverage under Part D.

CMS is also proposing that an entity seeking to offer creditable prescription drug coverage must attest to this actuarial equivalence (or non-equivalence) in its notice to Medicare beneficiaries and in a submission to CMS, and must maintain documentation of the actuarial analysis and assumptions supporting the attestation. CMS intends to describe the process for providing this disclosure, including guidance on the content, placement, and timing of the disclosure. However, CMS is concerned about the potential administrative burden imposed by this requirement and is therefore soliciting comments on the format, placement, and timing of such a notice.

CMS proposes requiring the employer to send an initial notice and a notice before any change in the plan takes effect, and to provide notice upon request. CMS seeks comment on how best to ensure that retirees receive timely and adequate notice of the creditable coverage status of their prescription drug coverage without imposing significant administrative burden on sponsors.

ERIC Member Survey Results *– Employers must notify beneficiaries if their coverage is "creditable". CMS states that timely notice is important, as is notifying retirees of any subsequent changes in their creditable coverage status. ERIC members were asked to select one of the approaches being considered by CMS as a best possible proposal. The results are as follows:*

- *71% chose "provide the sponsor with standard language to be inserted in the required disclosure materials routinely disseminated to their retirees";*
- *0% chose "require each sponsor to issue a separate notice to each Part D eligible enrollee;*
- *21% chose "require a HIPAA type 'Certification of Creditable Coverage' to eligible enrollees"; and*
- *14% chose "Other" (e.g., general notice if creditable and individual notice if not creditable, and one notice until changes – no annual requirements, etc.)*

ERIC Recommendation

ERIC recommends that CMS provide the sponsor with standard language to be inserted in the required disclosure materials routinely disseminated to their retirees. ERIC strongly believes that sponsors with creditable coverage should be able to include the notices in their annual general mailing. Requiring sponsors to send individual notices is too much of an administrative burden and cost. However, sponsors without creditable

coverage, may be required to send individual notices at the time of the initial determination or change. We also would like for the notice to be an addendum to material already distributed. CMS should seriously consider the requirement that notices of creditable coverage go only to beneficiaries if their coverage will not be creditable.

Issue for Discussion (Disclosure of Drug Benefit Value, Total Premium, Beneficiary Share)

Further, CMS seeks comments on whether it would be a significant administrative burden for group health plans and other sponsors to include in disclosures an indication of the value of their drug benefit, the total amount of the annual premium for the drug benefit, and the amount of the annual drug benefit premium that the beneficiary will be required to pay

ERIC Recommendation

ERIC believes that given the myriad of retiree plans offered by its member companies and the large number of retiree groups with varying levels of benefits, to indicate each retiree's prescription plan value and annual premium would be burdensome. Many member companies' prescription drug plans are part of and priced with a medical plan. Companies would have to separate the drug benefit from the medical plan and develop a methodology for reporting these figures. One member stated that "assuming the company used plan averages it would be misleading for many members whose utilization differed from averages and even the averages vary across the country."

Issue for Discussion (Form of Disclosure to CMS)

The MMA requires sponsors to disclosure creditable coverage status to CMS. CMS asked for comments on the possible methods of providing this disclosure.

ERIC Recommendation

ERIC recommends that employers provide CMS notice of creditable coverage in electronic form. Employers could send CMS an electronic file listing the names of retirees with creditable coverage at the start of the program. Employers could then periodically update this information with any changes in creditable coverage.

X. SUBSIDY AND RELATED ISSUES

A. The Preferred Timing of the Subsidy Calculation and Payment

Issue for Discussion (Methodology)

CMS is seeking to develop a methodology for making subsidy payments to employers that is both beneficial to employers and cost efficient. CMS assumes that most employers contract with a pharmacy benefit manager (PBM) to administer their prescription drug benefit programs. CMS proposed four alternatives in its proposed regulations.

ERIC Member Survey Results *- ERIC members responded in the survey to the CMS proposed four alternatives:*

- *21% selected the **CMS Choice** – CMS proposes to pay the subsidy on a monthly basis. By the 15th of the following month, plan sponsors are to submit the amount by which the gross drug-spending limit exceeded the cost threshold. CMS would pay the plan sponsor that amount by the end of that month.*
- *14% selected the **First Alternative** – A single payment would be made after the close of the year. Employers would submit data by the start of the fourth month after year-end; payment would be made for the year by the end of the following month.*
- *50% selected the **Second Alternative** – CMS would make interim payments throughout the year with a year-end settlement. Employers would develop an estimate of per capita subsidy payments based on the plan's claims history and rebates/discounts received in the period. Employers would submit the estimate and its basis at the same time as it submits its attestation of actuarial equivalence (as proposed, three months prior to the start of the plan year). Employers would be paid a percentage (70% for 2006 and 2007, 90% for subsequent years) on a periodic basis. By the start of the fourth month after the end of the year, the employer would submit documentation on claims costs and rebates. A final settlement would follow.*
- *14% chose the **Third Alternative** – CMS would make lagged payments based on actual experience on a periodic basis throughout the year with a settlement after year-end to reconcile rebates. Employers would make data submissions based on gross and allowable costs for the previous payment period. Review and payment would be made by the 15th of the following month. Settlement would take place after the start of the fourth month after the end of the year.*

ERIC Recommendation

ERIC recommends that CMS consider being flexible with regard to the methodology for making subsidy payments to employers. The survey results stress that one size does not fit all and therefore CMS should consider allowing several options.

Issue for Discussion (Payment Frequency)

In addition to the proposed payment methodology, CMS is interested in receiving comments on the frequency of payments. CMS suggested four options in its proposed regulations and asked for comment (i.e., annual, bi-annual, quarterly, and monthly).

ERIC Recommendation

Regarding timing, ERIC urges CMS to maintain as much flexibility as possible. Many PBMs have the ability to support the data requirements that monthly payment would entail, but there are also many employers who do not have that level of administrative support and would benefit from having the flexibility to submit their data and receive their payment only once per year. The 15-day turnaround time for submitting monthly payment requests and the 45-day deadline for year-end reconciliations seem rather tight, even for employers who have PBMs with excellent administrative abilities.

C. Possible Surety Bond Requirements

Issue for Discussion

CMS requested in its proposed regulations that employers comments on the level of administrative burden if a surety bond was required before an employer may receive the subsidy. We asked our members, "if CMS required a surety bond type of instrument or preferred creditor status in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation, would this be too much of an administrative burden?"

ERIC Recommendation

ERIC strongly recommends that CMS not require surety bond due to the extra cost and administrative burden involved. Also please keep in mind that any subsidy received by employers will be approximately one half the cost if the beneficiary was shifted to Medicare Part D. The potential risk to CMS does not justify the need for a surety bond.

C. Employers' Ability to Determine Medicare Part D Enrollment

Issue for Discussion

Despite an employer's intent to provide prescription drug coverage to retirees in lieu of Medicare Part D coverage, some retirees will mistakenly enroll in both employer-provided coverage and Part D and others who choose to enroll in Part D rather than their employer's coverage (which they have the right to do) will forget to notify their employer of the decision to switch coverage, with the result that vendors accidentally submit claims under the wrong coverage. Given the checkered history of the Medicare Secondary Payor (MSP) program and the problematic operation of the current voluntary data match program, it is in the interest of both employers and CMS to make sure

employers have appropriate means to minimize enrollment errors and detect inappropriate prescription drug claims as soon as possible before they are compounded by erroneous subsidy payments.

ERIC Recommendation

The best way to address this need is for CMS to make available to all employers real-time, HIPAA-compatible, electronic means of determining whether an individual is enrolled in Medicare Part D. To that end, ERIC strongly recommend that CMS adopt an electronic enrollment process for Part D through a CMS hosted Web site, a CMS hosted call center and a paper process. CMS should accept employers' electronic enrollment practices for enrolling beneficiaries in employer-sponsored prescription drug plans and develop a standard registration process that matches industry standards for third-party administrators.

D. Data Collection and Submission Issues

Issue for Discussion (Level of Detail)

The plan sponsors seeking the 28 percent subsidy will have significant data submission requirements and CMS intends to use those employer-supplied data to cross match with any Part D or Medicare Advantage prescription drug plan enrollees. CMS would require each plan sponsor to submit cost data for each of their qualifying covered retirees, including information about the period of time when these costs were incurred. CMS is considering three alternatives relating to the level of detail of this cost data.

ERIC Recommendation

Of the three choices outlined in the proposed regulations, the majority of the ERIC members participating in the survey selected the "submission of aggregate allowable costs data, but plan sponsors would be required to maintain the individual data for confirmation" option. ERIC recommends that CMS do not consider any additional data requirements other than the aggregate allowable costs data option due the obvious additional time required and the expense and administrative burdens.

Issue for Discussion (Data Files)

CMS asked plan sponsors to begin evaluating the availability of required information and plan for a creation of a file to contain the information. Additionally, CMS asked plan sponsors to comment on ideas to facilitate developing the most appropriate, efficient, and effective guidance regarding the data files.

ERIC Recommendation

ERIC solicited data file ideas from its members through the ERIC survey and the results are as follows: meet early with vendors; PBM industry should focus on this issue since

the pharmacy benefit manager industry has most of the data; we should include the actuaries in this process; since the data will be sourced from the health plans – they need to work together to define the format and some of the required data will not be known by September 30th and should be allowed to be submitted at a later date.

XI. ESTABLISHMENT OF COVERED DRUGS

Issue for Discussion

In its proposed regulations, CMS stated that it will request the U.S. Pharmacopeia (USP) to develop a model set of guidelines that consists of a list of drug categories and classes that may be used by prescription drug plan sponsors and Medicare Advantage organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. CMS expects that the model categories and classes developed by USP will be defined so that each includes at least on drug that is approved by the FDA for the indication in the category or class.

CMS further stated that as its work with USP gets underway, CMS will provide further detail on the USP classification in upcoming operational guidance to entities wishing to become prescription drug plan sponsors or Medicare Advantage organizations offering Medicare Advantage prescription drug plans. Also, CMS wishes to make clear that any guidelines established by the USP are applicable only to Part D benefits. CMS has asked for comments regarding standards and criteria that CMS could use to determine that a prescription drug plan sponsor or Medicare Advantage organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries.

USP is working to issue final formulary guidelines by the end of the year, after issuing its draft formulary guidelines on August 19, 2004. The guidelines contain 43 therapeutic categories and 138 pharmacological classes. Health plans will not be required to adopt the guidelines, but those that do will be considered to have met standards for a drug benefit acceptable to CMS. Formularies not meeting the guidelines will be subject to review by the agency to ensure they do not restrict access t drugs by seniors.

ERIC Recommendation

ERIC believes there should be a balance between guidelines that could break the budget and those that place burdensome restrictions on important medications. We stress that the affordability of the benefit will be threatened if too many drug categories are included in the model set of formulary guidelines. USP should add only categories that are based on pharmaceutical and medical science. It appears that the draft guidelines do not provide the flexibility given pharmacy benefit managers in the commercial market where some formularies have as few as 50 categories. ERIC further recommends that

USP not move any additional classes from the recommended subdivisions into the required pharmacological class section.

XII. CONCLUSION

Regarding timing issues we recommend that CMS issue substantial guidance and/or the final regulations by December 31, 2004. Any release of information before January 2005 will assist in allowing employers to make decisions and comply with upcoming deadlines. The overall timing issues affect employers that plan to accept the retention subsidy as well as those who plan to wrap around Medicare Part D coverage. In addition, we are particularly interested in information regarding the calculation of actuarial equivalence and the underlying actuarial value determinations. We strongly request that CMS use its discretion to provide maximum flexibility for employer plans under the final regulations and any interim guidance.

Finally, we anticipate that some groups commenting will continue to urge CMS to include certain employer requirements in the final rules, i.e., require employers to continue prescription drug coverage for retirees; require employers to disclose actuarial equivalency calculations to non-governmental groups; give individuals the right to challenge an employer's actuarial equivalency determination; and restrictions on how an employer may use subsidy payments. There is no statutory basis for these requirement and we request CMS to stay within the statutory authority delegated by Congress.

As requested by CMS, ERIC is submitting these comments (without any duplicates by mail or by hand) electronically to www.cms.hhs.gov/regulations/ with the text attached in the preferred Microsoft Word format.

Sincerely,

[signed]

Mark J. Ugoretz
President
The ERISA Industry Committee