TESTIMONY OF
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ON
TITLES I AND II: FEATURES OF THE PROPOSED REGULATIONS
BEFORE THE
SENATE COMMITTEE ON FINANCE

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Chairman Grassley, Senator Baucus, distinguished members of the Committee, thank you for inviting me here today to discuss the most dramatic and innovative modifications to the Medicare program since its inception in 1965. I want to thank the Committee members for your interest in the Medicare program, your hard work on the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and your support of the Centers for Medicare & Medicaid Services (CMS) as we work to implement this important new law.

The two regulations we are here to discuss today lay out CMS' proposal for delivering new services and benefits created by this Congress and the Administration in the MMA. This new law provides better benefits -- including prescription drug savings of more than 50 percent for the average senior without coverage -- and improved access to health care services through Medicare. These proposed regulations create a new voluntary prescription drug benefit under Medicare, as well as new health plan choices, improved health care for rural America and improved preventive care benefits.

The new prescription drug benefit will allow all Medicare beneficiaries to enroll in drug coverage through a prescription drug plan or Medicare health plan with Medicare paying, on

average, for 75 percent of the premium for standard Medicare drug coverage. Additional benefits for Medicare beneficiaries who have limited means will cover, on average, approximately 95 percent of their drug costs. The new benefits will also provide support for employers or unions that provide their retirees with drug coverage making it possible for those sponsoring institutions to provide more help to the retirees. All the new Medicare benefits are voluntary, as seniors can choose to keep their existing traditional coverage. With these regulations we are delivering on our promise to America's seniors to provide better benefits, leading to better health and real savings on their out-of-pocket medical costs, including prescription drugs.

The MMA is a substantial piece of legislation, containing 227 provisions requiring implementation by the end of 2004 alone. As shown in the attached charts, CMS has implemented 149 of those provisions, or 66 percent, and is currently in the process of finishing the remaining 78. I might also point out that of those due by August 30, 2004, CMS has implemented 91 percent, with the remaining handful in progress. Just for example, CMS published the regulation setting up the Medicare approved drug discount card on December 15, 2003, just seven days after President Bush signed the MMA into law. CMS is well on its way to full and timely implementation of this important legislation.

Background

Overall, Medicare has clearly been a success in providing needed care to America's seniors and disabled, but it has not kept pace with modern health care in its lack of coverage of most outpatient drugs and in failing to provide access to coordinated-care options that reduce costs.

At Medicare's inception in 1965, the use of drugs to treat disease was not nearly as prevalent as it is today. As a result, despite assistance offered through State Medicaid programs, Medigap plans, employer retiree plans and other insurers, approximately one-quarter of Medicare beneficiaries lack basic prescription drug coverage. The lack of prescription drug coverage is a particular problem for beneficiaries with limited financial means, and those with catastrophic drug costs, situations that force difficult choices. Under the MMA, all of these beneficiaries have the option of new, subsidized, voluntary drug coverage, as well as new support to keep their current retiree coverage secure.

In addition to the standard drug benefit, which is available to all beneficiaries, the MMA and the proposed regulations provide several approaches for beneficiaries to get even more comprehensive coverage. For example, low-income seniors and people with a disability who have limited means – about a third of all people with Medicare – will get access to comprehensive coverage, with no or limited premiums, deductibles, co-payments or coinsurance, and no gaps in coverage. Medicare beneficiaries with retiree coverage may benefit from a set of options to get affordable, enhanced coverage, including a new retiree drug subsidy as well as options for employers and unions to wrap around Medicare coverage or offer Medicare-subsidized drug coverage themselves. Beneficiaries who are contributing to their own coverage, through an employer's retiree plan, for example, may be able to use the new Medicare subsidies to obtain enhanced coverage at a lower cost.

The new Medicare law and the proposed rules also allow states the flexibility to "wrap around" the comprehensive coverage for certain low-income beneficiaries in addition to providing net

savings to states by providing comprehensive coverage for "dual-eligible" beneficiaries (those eligible for both Medicare and Medicaid) and providing new subsidies for state retiree coverage. In addition, state pharmacy assistance programs, other individuals, and charitable organizations can contribute toward a beneficiary's out-of-pocket costs and still have those contributions count toward catastrophic coverage.

Finally, through the new Medicare Advantage (MA) program, beneficiaries will have access to a variety of modern integrated health insurance plans, including preferred provider organizations (PPOs). PPOs are the most popular health plans for younger Americans who are covered by commercial health insurance plans, but until now have not been prevalent in Medicare, particularly in rural areas.

The Regulations

The focus of today's hearing is the two proposed regulations published by CMS on August 3, 2004, which contain the Agency's recommendations for implementing Titles I and II of the MMA. These proposals take many important steps forward toward implementing the new law, and we are very anxious to "get it right," so that Medicare beneficiaries can get the maximum help from all the new benefits and choices made available through MMA. Consequently, we have also asked for comment on a number of options for implementing the law, and we are conducting a major public outreach effort to make sure we are hearing from all perspectives.

One of the primary goals of the regulatory process is to invite the public to work with the Federal government in formulating a means to best implement the law as passed by Congress. We

consulted widely with the private sector and other government entities during the development of these rules, and now, to educate ourselves as thoroughly as possible prior to finalizing the rule, we are soliciting public comments on all aspects of the proposals.

These two rules contain a number of instances where the Agency has specifically petitioned the public to assist in deciding which course to take when there are multiple objectives and goals that we want to achieve simultaneously. We are obtaining extensive public comment from experts in the fields covered by these rules and will use their comments to shape the final regulations, which are on schedule to be published in January 2005, so that the programs can go into effect in 2006.

Since announcing the regulations on July 26, CMS has been actively engaged in soliciting public input. We have held some twenty open door forums to educate the public and obtain feedback. These national conference calls are announced through our website and e-mail alerts, typically have background materials associated with them, and are geared toward specific concerns with the Medicare and Medicaid programs. Literally thousands of people from the private sector and other outside groups have participated in these calls and have provided CMS with the opportunity to explain and receive feedback on these two proposals.

CMS central office and regional office staff have also held numerous outreach and town hall meetings to both explain and solicit comment on various aspects of our work to implement the MMA. In addition to the open door forums and outreach events, Secretary Thompson and I have

personally been very active in meeting with Congressional and outside groups to hear their concerns and suggestions, and to explain our proposals.

The Drug Benefit

Under the new Medicare drug benefit, all Medicare beneficiaries will have access to a voluntary drug benefit. A typical beneficiary without drug coverage today, who is not eligible for low-income benefits, could see their total spending on drugs drop by 53 percent, or nearly $1,300. The savings for the standard drug benefit come from two main sources. First, beneficiaries who enroll in a Medicare drug plan, regardless of whether they qualify for low-income assistance or not, will pay lower prices for the drugs they purchase because the drug plans will be negotiating discounted prices with drug manufacturers. Prescription drug plans (PDP) and Medicare Advantage plans offering prescription drug coverage (MA-PD), will face strong pressures to keep drug costs low and pass those savings on to their enrollees. This negotiation is expected to reduce drug prices for beneficiaries by 15 percent initially, rising to 23 percent within 5 years. Even beneficiaries who have drug coverage aside from that offered through a Medicare drug plan can avail themselves of these lower prices by purchasing through the Medicare plan. These cost savings are expected to result from strong competitive pressures, including transparency in drug price and benefit information, for drug plans to negotiate discounted prices and manage drug costs to obtain the lowest costs possible while providing the drugs that beneficiaries need, and to pass these savings on to beneficiaries.

The proposed rule outlines an approach similar to the one used by the Federal Employees Health Benefits Program and other large health care payers. This approach is expected to provide the

best discounts on drugs – discounts as good as, or better than, could be achieved through direct government negotiation, resulting in prices that will be substantially better than Medicare's prior experience with price regulation for the drugs that it currently covers under Medicare Part B. We have seen such competition yield beneficial results in drug prices already, in the Medicare prescription drug discount card program, where numerous independent studies have found that prices are substantially lower on very broad drug formularies, as purchasing power combined with competitive pressures and public release of drug prices have driven prices down. Further, these price reductions are on the drugs that beneficiaries commonly use, including many drugs not included in the formularies of government-run drug plans. We expect prices under the drug benefit to be reduced even further from those available under the Medicare approved drug discount card program. With effective price negotiation and other tools to lower costs on the drugs that beneficiaries want, no Medicare beneficiary ever needs to pay anything close to list prices again.

The second way that the drug benefit will offer savings to Medicare beneficiaries is through the Federal government's subsidization of their monthly premiums and catastrophic costs. Medicare's approximately 75 percent subsidy, on average, for the standard drug coverage is expected to result in a beneficiary premium for this coverage costing about $35 a month in 2006. That is, for the first time, Medicare will be paying about $105 a month, per beneficiary toward the cost of drug coverage for all beneficiaries. (As noted above, low-income beneficiaries get even greater help.) In this subsidized coverage, in 2006, beneficiaries enrolling in the standard benefit will pay an annual deductible of $250, plus 25 percent of drug costs, up to an initial coverage limit of $2,250. After that point, once the beneficiary reaches $3,600 in out-of-pocket

spending, the Federal government and plans will pay about 95 percent of the beneficiary's drug costs. There will be no annual plan maximum, and coverage will never run out. Congress designed the drug benefit so that the number of beneficiaries who will have to fill in the gap between the initial coverage and the catastrophic coverage would be minimized. CMS estimates that more than two thirds of Medicare beneficiaries will not have to pay any money toward filling that gap. It is important to note, as well, that drug plans are required to pass on negotiated prices to the beneficiaries on all drug purchases. As a result, even when beneficiaries are responsible for the full cost of the drugs they purchase, the negotiated discounts mean that prices for those drugs will be lower than they would if the beneficiary did not belong to a plan.

The subsidy Medicare provides for standard drug coverage can be combined with other sources of assistance to provide even greater coverage. State pharmacy assistance programs, charitable organizations, and other individuals can contribute to beneficiary out-of-pocket costs and have those contributions count as "true" out-of-pocket expenditures when it comes to calculating how close the beneficiary is to reaching the $3,600 in out-of-pocket spending required to trigger catastrophic coverage. Beneficiaries, employers, and others can also use some of their existing contributions to buy supplemental or "high-option" coverage to enhance the standard coverage, while still obtaining substantial overall savings compared to what they or their employer are paying now because of the new Medicare subsidies.

Beneficiary Protections

The MMA incorporates substantial beneficiary protections from traditional Medicare and from the Medicare+Choice program. It also creates new rights and protections that are specific to the drug benefit, including:

- Guaranteed issue – PDPs, and the MA-PD plans, must accept all eligible enrollees who reside in their service area, regardless of age or health status.
- Uniform benefits and premiums – Plans must provide all their enrollees with the same benefits and charge a community-rated premium, which is the same for all enrollees in that region.
- Formulary protections – Plans' formularies must include two drugs from every therapeutic category and class, with only a few exceptions. Plans must also develop the formulary with the help of a pharmacy and therapeutic committee that includes practicing pharmacists, physicians, and an expert in geriatric care. This committee will use the best scientific evidence on drugs' safety, efficacy, and side effects to enhance quality while controlling costs. CMS is working with U.S. Pharmacopeia to develop a model therapeutic categories and classes of drugs, and is also developing guidance on all major aspects of a drug benefit to assure that drug coverage reflects modern medical practice and does not discriminate against any particular type of beneficiary.
- Grievance and appeals requirements – Plans will be required to have a grievance and appeals process that allows beneficiaries to challenge denials based on the formulary. A successful challenge would result in the plan granting what is called an exception, under which, a non-formulary drug could be covered, or a non-preferred drug could be covered

under the terms applicable for a preferred drug under certain conditions. We are proposing that plans have reasonable flexibility to design their exceptions criteria. As part of this process, the prescribing physician would have to determine that the preferred drug (or all the formulary drugs) either would not be as effective for the individual, or would have adverse effects for the individual, or both. Physicians and authorized representatives (such as a family member) can assist beneficiaries in challenging a plan's formulary or its tiered cost-sharing, though, by law, only the enrollee or authorized representative can file an appeal to an outside, independent entity.

- Information – Plans must provide a wide range of information to beneficiaries, including a summary of benefits, how to access the benefits, how the formulary works, and how the plan's medication therapy management program works. They must also provide, upon request, information on the grievance and appeals process and how the plans have performed in this area. As part of our efforts to inform beneficiaries, Medicare also expects to continue many of the features of our current "Price Compare" program for drugs, so that beneficiaries can find the best prices on the medicines they need, as well as learn about other ways to save like substituting less costly generic drugs.
- Customer service – Plans must respond to beneficiary questions in a timely manner, including responses through a toll-free telephone number and by placing information on the Internet. They must also provide beneficiaries with a clear explanation of their benefit use and how much prescription drug spending they have incurred during the year, as well as how close they may be to the catastrophic coverage benefit.
- Pharmacy access – Plans must assemble broad networks of retail pharmacies to provide convenient access for beneficiaries, such that 90 percent of urban enrollees live within 2

miles of a network pharmacy, 90 percent of suburban enrollees live within 5 miles, and 70 percent of rural beneficiaries live with 15 miles.

- Cost management – Plans are required to have cost management programs that save beneficiaries money with tools such as promoting the use of generic drugs and more cost-effective therapeutic substitutions.
- Therapy management – Plans must have medication therapy management programs to help beneficiaries who have multiple chronic conditions, use multiple drugs, and expect to have high drug costs make sure they are taking safe combinations of drugs and using the drugs properly.
- Generic drug information – Plans and pharmacists are required to inform beneficiaries at the point of sale if they could save money by using a generic drug instead of a more expensive brand name drug. Generic drugs are certified by the Food and Drug Administration as just as safe and effective as their brand name counterparts, yet they often cost a fraction of the brand price. As noted above, Medicare has already started providing information on less costly alternative drugs and intends to continue to do so.
- Privacy – Plans must maintain privacy and confidentiality of patient records.
- Collecting satisfaction data – Plans are also required to participate in consumer satisfaction surveys, which allow enrollees to rate their experience with plans. The ratings will be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use when choosing plans.

Low-Income Subsidy

One of the major points I would like to emphasize is the substantial additional assistance available to lower income individuals with Medicare. Under the proposed rule, it is estimated that nearly 11 million beneficiaries with limited incomes and assets will participate in the low-income subsidy, receiving substantial additional help from Medicare. About 6.4 million "dual eligible" low-income beneficiaries will pay no premium, or a limited premium, no deductible and nominal co-pays or as little as $1 or $3 per prescription. For these beneficiaries, ***the Medicare benefit will pay, on average, more than 95 percent of their drug costs.*** Of the "dual eligible" beneficiaries, about 1.5 million who are institutionalized are totally exempt from cost sharing. They pay no premiums, or a limited premium, no deductibles, and no co-payments.

About 3 million Medicare beneficiaries who are not full-benefit dual eligibles, but whose incomes are less than 135 percent of the federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) and who have limited assets will also pay only a few dollars per prescription, with no premium, or a limited premium, and no deductible. ***Medicare will cover 95 percent of their drug costs on average.***

For about 1.5 million beneficiaries with incomes less than 150 percent of the federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006, the Medicare benefit calls for 15 percent co-pays with a sliding-scale premium, ***covering 85 percent of their drug costs on average.*** Among all enrollees receiving a subsidy, we expect the new comprehensive drug benefit to attract more than 1 million beneficiaries with limited means who, while eligible for Medicaid benefits (including QMB, SLMB and QI benefits), have not previously enrolled.

Altogether, with the straightforward means test proposed in the rule, about a third of all Medicare beneficiaries are eligible for low-income assistance with no gaps in coverage, and limited, or no premiums, deductibles, or co-payments. This coverage is expected to be worth almost $3,500 on average in 2006 and can mean tremendous savings in drug costs. For example, beneficiaries with incomes below 135 percent of the federal poverty level and meeting the asset test can get a lifesaving drug that costs $40,000 or more for at most $60 per year.

We believe that most people eligible will apply for the low-income subsidy and enroll in a plan offering prescription drugs because of the high value of the drug benefit and the unprecedented outreach activities by Medicare and its partners, particularly the Social Security Administration (SSA). This includes about a million beneficiaries who are also eligible for Medicaid, but who previously have not enrolled. To make sure these people can receive drug coverage January 1, 2006, we are working with SSA and the States to have the systems in place so that eligibility determination for the low-income subsidy can be done beginning in mid-2005. In the spring of 2005, SSA, CMS and our partners will begin comprehensive community-based communication efforts to reach the people who are potentially eligible for the low-income subsidy and encourage them to complete a timely application and enroll in a plan offering prescription drug coverage early in the open enrollment period.

Asset Test

The MMA requires CMS to utilize an asset test in determining whether certain low-income beneficiaries are eligible to receive the comprehensive assistance available under the new drug

benefit. The public should know that this asset test specifically does not count items such as the family home, household goods, personal effects, vehicles, burial plots, and a number of other types of resources. CMS has proposed a straightforward asset test that would count only liquid assets such as stocks, bonds, checking and savings accounts, plus real estate holdings other than a primary residence, in determining a beneficiary's qualification for the low-income subsidy. We have also proposed a methodology for verifying income and resources that would eliminate the need for extensive paper documentation.

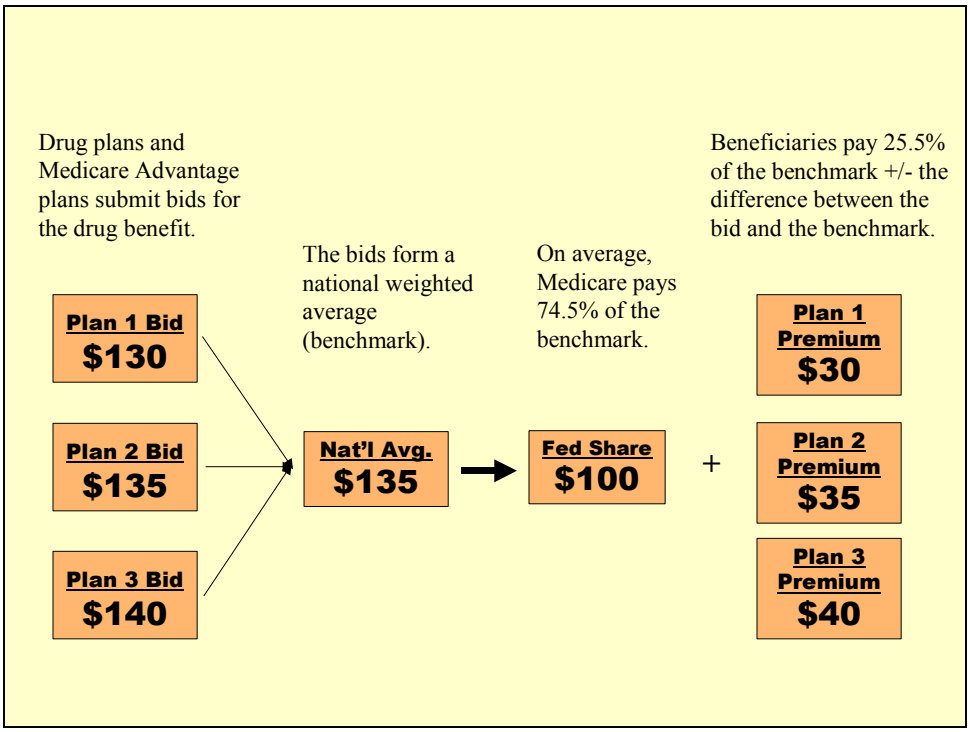
Competition and Lower Drug Prices

The proposed drug benefit rule describes a competitive process for Medicare beneficiaries to pay low premiums, have access to low drug prices, and receive high-quality pharmacy services. The process includes direct Medicare oversight to make sure that the costs and quality of plan bids reflect plans' actual costs.

Beneficiary premiums for the new drug benefit will be determined through a competitive bidding process. The premiums for standard coverage are expected to average in the range of $35 per month in 2006. The specific premium for each plan will be determined by its bid.

By law, and as reflected in the proposed rule, all PDPs and MA plans wishing to provide a drug benefit will submit a bid for the cost of providing the drug benefit to a typical beneficiary in the area they seek to serve. The typical beneficiary will be a statistical average of age and health status for the nation. CMS will review the bids, and the portion of all the approved bids related to basic benefits will be compiled into a national weighted average, which serves as a benchmark

for purposes of setting premiums. The weights will be the plans' enrollment shares in the prior year. For the first year of the program, CMS has proposed a system to estimate weights. The premium for each plan's drug benefit will be 25.5 percent of the benchmark, plus or minus any difference between the benchmark and the plan's bid.



Note: This illustration is slightly simplified and liberally rounded. It assumes equal enrollment weight on each of the five plans and bids for basic benefits only. Technically, an adjustment factor modifies the beneficiary premium percentage to account for reinsurance payments, which are not included in the plan bid amount. However, the purpose of that adjustment factor is to ensure that, on average, the premium represents on average 25.5 percent of the total cost of the benefit, including reinsurance, which is reflected in the graphic.

PDPs seeking to serve the Medicare population will negotiate discounts with manufacturers that they must pass on to beneficiaries in the form of lowered premiums or improved services in order to compete for beneficiaries. Plans that fail to secure highly competitive prices will not be able to offer attractive premiums to beneficiaries, and will lose market share to plans that do a better job of lowering prices.

Competition among private plans to secure favorable drug pricing has been a successful model for other government programs, including the Federal Employees Health Benefits Plan (FEHBP). FEHBP leaves price negotiations up to the private plans that provide coverage for all enrollees, including federal retirees.

As risk-bearing insurers, the new drug plans and MA plans will have every incentive to drive hard bargains with drug manufacturers. Consequently, CMS and the Congressional Budget Office (CBO) expect that the private negotiations between plan sponsors and drug manufacturers will achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. Competition, therefore, will be used to the advantage of beneficiaries and is expected to lower the prices they pay.

Medicare will empower and support beneficiaries in "comparison shopping" by providing specific information on premiums, covered drugs and their prices, and pharmacies and pharmacy services. The competition engendered by making this type of information public has acted to substantially lower prices in the Medicare approved prescription drug discount card program from levels previously borne by our seniors and we expect similar competitive forces to push prices down under the Part D drug benefit.

Using competition to drive price negotiation will maximize savings on drug prices, as well as, or better than when government does direct price negotiation. For example, Medicare approved discount drug card sponsors are realizing higher discounts than the California's Medicaid

program. Until recent reforms made by the MMA, Medicare's prices for drugs currently covered under Part B, and paid for based on rates set by the Federal government, consistently exceeded market averages by significant amounts. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree. And since drug plans are exempted from Medicaid's best price rules, they can negotiate better prices than those paid under Medicaid without having to extend the discounts elsewhere, providing further incentives to do better than government price regulation.

In addition to price negotiation, plans will use a range of formulary design tools and drug utilization management techniques to reduce total spending. Together, we anticipate discounts and cost management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. The increase over time is due to the market maturing and seniors migrating to more efficient plans, and accounts for the fact that lower drug costs may increase drug utilization for many beneficiaries.

In addition, beneficiaries will also have formulary coverage and pharmacy services that are more responsive to their own preferences than in a government-run plan. In a government run system with a single, set formulary, patients may encounter situations where it is not possible to obtain coverage for the drugs they need. Thus, the approach we are adopting is intended to maximize price discounts while assuring up-to-date coverage of the drugs that beneficiaries prefer, not the drugs that the government chooses in order to limit costs. CMS is seeking comments on steps that will achieve the maximum drug savings possible, without compromising beneficiaries'

access to the medicines they need. For example, the proposed rule seeks comment on how to best design the drug benefit information, including personalized information on drug prices and information about formularies and pharmacies, so beneficiaries will be able to know how much they will have to pay for their drugs, similar to the information currently provided by Medicare for the Medicare approved drug discount card program.

As required by the MMA, CMS has worked with the U.S. Pharmacopeia to establish model guidelines for the categories and classes of drugs to be included in plan formularies. The guidelines are a starting point for structuring formulary categories and classes. However, they allow plans the flexibility to develop their own formularies, which CMS will review to ensure adequacy and nondiscrimination according to publicly reviewed principles that make sure patients have reasonable access to important drugs. CMS has invited public comment on these guidelines and is also conducting an extensive process for public input on the model formulary classification systems and formulary oversight.

Enrolling in a Drug Benefit Plan

The new Medicare drug benefit is designed to be voluntary. In general, Medicare beneficiaries must choose to enroll in a plan offering prescription drug coverage, either a MA plan offering drug coverage or a stand-alone PDP. This approach is different from the "opt-out" rule that exists in Part B, where people are automatically enrolled in the program when they turn 65 unless they notify Medicare otherwise.

Beneficiaries without drug coverage from some other source, comparable to that offered under the Medicare program, who choose to not sign up at the first opportunity, will face a late enrollment penalty if they enter the program at a later date. This late enrollment penalty is similar to a penalty currently in place for late enrollment in Medicare Part B insurance and its purpose is to encourage beneficiaries to enroll when eligible in order to avoid situations where only the sick sign up for insurance, thus skewing the risk pool for those participating in the coverage.

Coverage for the new drug benefit begins January 1, 2006. Initial open enrollment for the new benefit will begin November 15, 2005, and will run for six months, ending May 15, 2006. In subsequent years, open enrollment will run from November 15 to December 31 for the next benefit year. The enrollment periods for all Medicare plans offering drug coverage and Medicare Advantage plans will run at the same time.

Any full dual eligible individual who fails to enroll in a PDP or MA-PD plan would be automatically enrolled, on a random basis, into a PDP that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries.

The MMA also establishes special enrollment periods (SEPs) beyond the initial and annual periods. Special enrollment periods allow an individual to disenroll from one PDP and enroll in another PDP without penalties, outside of the annual period. Special enrollment periods are available for several reasons, including:

- Involuntarily losing creditable drug coverage, or having such coverage reduced below the level that would qualify it as creditable. Creditable coverage is coverage that is at least equivalent to that offered under the standard Medicare drug benefit. Beneficiaries who do not enroll in a PDP or MA-PD plan when first eligible, but maintain creditable coverage through some other source, such as an employer, would be allowed to sign up for Medicare coverage during an SEP and would not be subject to penalties if their coverage was lost or reduced involuntarily.
- Individuals who are subject to enrollment errors, specifically those caused through misrepresentation, inaction, or error by the Federal government will be allowed to enroll under an SEP.
- Individuals who are determined to be full dual eligibles after the initial enrollment period are provided with an SEP. This would also provide these individuals who have been automatically assigned to a plan the opportunity to change PDPs or MA-PD plans at any time.
- An individual who enrolls in an MA-PD plan upon first becoming eligible for benefits under Part A at age 65 and then discontinues that enrollment and elects coverage under original Medicare and a PDP at any time during the 12-month period beginning on the effective date of the MA-PD plan election is eligible for an SEP.
- The PDP terminates its service area or is terminated in the area in which the individual resides.
- The individual moves out of the plan's service area.
- The individual demonstrates to us, in accordance with guidelines that we establish, that the PDP offering the plan substantially violated a material provision of its contract, or the

PDP materially misrepresented the plan's provisions in marketing the plan to the individual.

- In addition, MMA provides for a continuous open enrollment period for institutionalized individuals throughout the year.

Eligibility Determination Process

Eligibility for low-income subsidies may be determined by state Medicaid agencies or by SSA. Individuals will be able to apply for the subsidy at either agency. SSA is implementing a computer scannable application as well as an Internet based application. As a result, we expect that the States and others partners will use the SSA application and eligibility determination process.

If an individual is determined to be eligible for a subsidy, that determination will remain effective for up to one year. The agency that processes the determinations will determine the manner and frequency for re-determinations and the process for appeals. It is important to remember that people who apply for the subsidy must still enroll in an MA-PD plan or PDP of their choice to access the Medicare covered drug benefit.

Keep in mind that beneficiaries who are dually eligible for Medicare and Medicaid, about 6.4 million, as well as those in a Medicare Savings Program (QMB, SLMB, and QI beneficiaries – about one million individuals) will not have to complete an eligibility application. These beneficiaries are deemed eligible and will automatically qualify for the subsidy. Non-full benefit dual eligible individuals will still need to enroll in a plan offering prescription drug benefits.

We are working closely with SSA as they develop the model, simplified application form and process for determination and verification of an eligible beneficiary's income and resources (based on our straightforward asset test). A draft application has been focus group tested with Medicare beneficiaries and is being revised based upon their comments. SSA is working hard to make sure that the application is readily understandable by beneficiaries.

Beneficiaries will be able to complete the application themselves or with the help of State or other community based support organizations. SSA will accept the applications through the mail or it can be dropped off in person, and beneficiaries can also apply over the phone or on the Internet, making it even easier for community organizations to help them sign up. The application form will consist of an attestation regarding a beneficiary's income and resources. The straightforward asset test proposed by CMS, as discussed above, means that beneficiaries will not have to gather together volumes of files, nor do they need apply in person. In fact, the goal of the application process is to facilitate completing the application at home without the need to visit a government office. SSA and the States will be able to verify most information through data matches. States and SSA may need to request some follow up documentation to verify information, if data matches do not provide the needed verification.

We have convened a workgroup with States, SSA, and CMS to work through a variety of issues regarding implementing the low-income subsidies. We intend to work together to develop a system that:

- ensures timely and accurate data sharing on the deemed population;

- facilitates filing applications via the internet, the telephone, or the mail;
- works with community organizations to help people complete applications;
- minimizes the paperwork burden on applicants; and
- exercises appropriate stewardship of federal funds.

Savings to the States

States are projected to see net savings of about $500 million in 2006 and $8 billion in the first five years of the drug benefit. Net savings are projected for states that provide Medicaid-only coverage, states with Medicaid and state pharmaceutical assistance plans, and states with Medicaid and "Pharmacy Plus" (Section 1115 waiver) plans. The sources of savings are as follows:

- *Medicare drug coverage for dual eligibles:* Starting in 2006, full-benefit dual eligible beneficiaries (Medicare beneficiaries eligible for a state's full range of Medicaid benefits, including drug coverage) will receive most of their prescription drug coverage through Medicare rather than through their state Medicaid programs.
- *New subsidies for state retiree health programs:* As employers, states can qualify for the new retiree drug subsidies available to employers and unions that furnish qualified retiree drug coverage to Medicare beneficiaries.
- *Relief for State Pharmaceutical Assistance Programs:* States that operate State Pharmaceutical Assistance Programs (SPAPs) and "Pharmacy Plus" waivers providing subsidized drug coverage to individuals who will be eligible for the Medicare prescription drug plan will gain substantial savings starting in 2006, when Medicare begins providing very generous coverage for beneficiaries with limited means. As a

result of the savings from beneficiaries who qualify for the low-income Medicare coverage, States can "wrap around" the Medicare benefit to maintain or enhance benefits, at a lower cost to the State. SPAP assistance with beneficiary cost sharing would count toward the out-of-pocket catastrophic threshold. As a result, SPAPs will be able to continue to provide as generous or more generous assistance for the beneficiaries who receive coverage through state programs now, at a lower cost per beneficiary for the States because of the availability of the Medicare drug benefit. States will also be able to restructure existing "Pharmacy Plus" programs to wrap around the Medicare prescription drug benefit.

CMS intends to work closely with States, through comments, the new "SPAP Commission" and many other forums, to ensure that the drug benefit delivers better coverage and lower costs for beneficiaries in light of the individual circumstances of each state.

Retiree Coverage

The MMA contains new subsidies designed to encourage employers and unions to continue providing high quality prescription drug coverage for their retirees. This alternative retiree drug subsidy provides special tax-favored payments to sponsors of qualified retiree PDPs. The retiree drug subsidy program has highly flexible rules that permit employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D drug benefit, and using the retiree drug subsidy to reduce the cost of providing generous coverage. That is, total support for retiree drug coverage is likely to increase as financial support from the new Medicare retiree drug subsidy

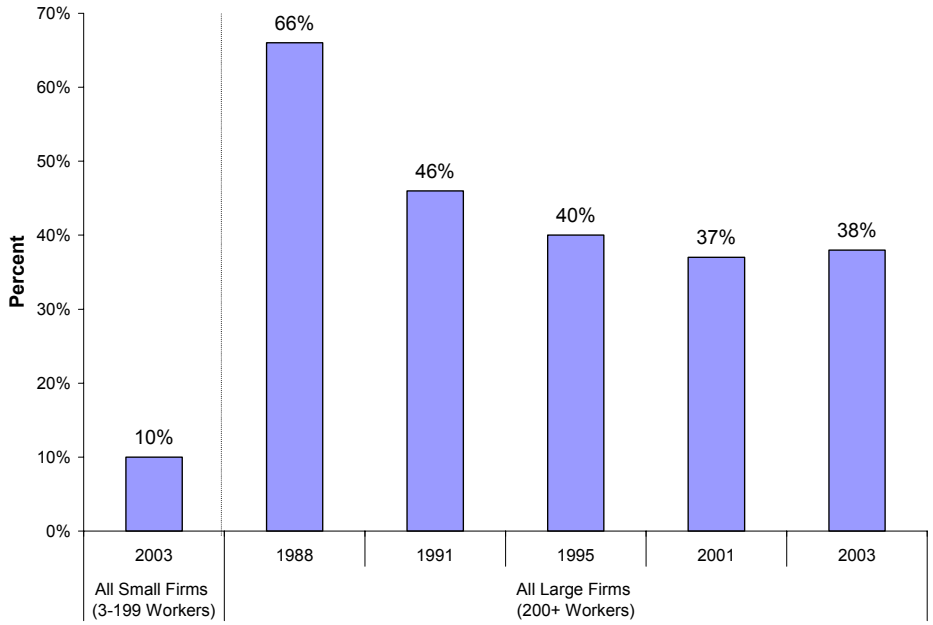
and the Medicare prescription drug benefit augment employer and union contributions. This may result in retirees spending less on average – possibly significantly less - for prescription drug cost sharing and premiums combined, than they would without the new law.

Sponsors of employer and union plans who offer a drug benefit as good as, or better than, Medicare's standard drug benefit will be able to apply for the subsidy, which is estimated to roughly average $611 per beneficiary in 2006. The after tax nature of the retiree drug subsidy payments effectively increases the value of these payments for employers that are subject to the corporate income tax. For firms with a marginal tax rate of 25 percent that translates into a subsidy of $815, and for firms with a marginal tax rate of 35 percent, the value of the subsidy rises to $940. Our proposed rule presents several options on how to define the qualifying criteria for employers and unions who would like to receive the subsidy. We are currently accepting comments on these options and are committed to maximizing participation, preventing windfalls and limiting costs to the treasury.

Retiree coverage has been in decline for many years

Employer-sponsored retiree health insurance has been an important source of drug coverage for many Medicare beneficiaries. However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. As prescription drug costs have risen, employers have shifted more of those costs to their retirees, and many employers have ceased offering retiree health coverage altogether.

Percentage of Firms Offering Retiree Health Benefits, 1988-2003



Source: Kaiser/HRET Survey of Employer Sponsored Health Benefits: 2001, 2003; KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, 1995. The denominator is all firms that offer health benefits to active workers.

In 1988, 66 percent of large employers that offered health benefits to active workers also offered retiree health benefits. In 2003, only 38 percent of large employers offered them. During the same year, only about 10 percent of small firms that offered health benefits to active workers also offered retiree health benefits. The picture is even starker for future retirees, who have been disproportionately affected by most of these changes.

The Retiree Drug Subsidy

Medicare is helping employers continue to provide retiree health care coverage. The new retiree drug subsidy will support employers and unions who continue offering high-quality prescription drug coverage as Medicare's own benefit comes online, or who enhance their coverage by using the new support to offer better coverage at a lower cost. The proposed regulation reflects our

four objectives of: maximizing the number of retirees benefiting from the retiree drug subsidy, avoiding windfalls to employers, minimizing administrative burden, and not exceeding budget estimates. In doing so, our objective is to get the maximum possible increase in support for drug coverage for all retirees, and so we are considering a range of potential options discussed in the preamble of our Title I proposed regulation, each of which may help us achieve our key objectives. We seek comments and are conducting extensive public outreach on how best to accomplish our objectives.

To maximize the continuation and enhancement of retiree coverage, CMS is proposing that the Medicare retiree drug subsidy be designed to be flexible enough to enable employers and unions to obtain the subsidy without disrupting their current coverage. Many employers will be able to continue the same drug plans they offer today, uninterrupted, while receiving a substantial Federal subsidy to reduce their costs. Retirees can choose to enroll or not enroll in the new standard Medicare drug benefit while remaining in their employer or union plan, which may also offer better coverage.

Employers also have the option of declining the retiree drug subsidy and encouraging their retirees to enroll in Medicare's new PDPs, or in an MA-PD plan, while providing them with extra help. These approaches as well can lead to drug savings for both retirees and employers. There are several ways that employers could supplement the standard Medicare drug benefit:

- They may pay for supplemental coverage through an enhanced Medicare plan that fills in more of the cost-sharing, just as employers "wrap around" Part A and Part B Medicare benefits today;

- They may set up their own external supplemental plans and coordinate benefits with the Medicare drug plans, providing extra help with cost sharing;
- They may also choose to provide assistance with the basic drug premium for Medicare; and,
- They may choose to set up special prescription drug plans, or Medicare Advantage plans, for their retirees. CMS plans to use its waiver authority to allow employers to make special arrangements with PDP and MA-PD plans for their retirees. These waivers would allow employers and plans to provide more flexible benefits and to limit enrollment to the retiree population.

Many factors may influence the responses of employers and unions to the new subsidy for retiree drug coverage. As noted above, one critical decision is whether employers will want to remain the primary insurer of retiree prescription drug costs and receive the retiree drug subsidy, or shift to becoming a secondary payer by wrapping around Medicare coverage, with Medicare subsidizing retiree drug costs by becoming the primary insurer. Either way, the actual benefits received by retirees could remain unchanged or increase, but at a lower cost to the employer, making both approaches to comprehensive drug coverage indistinguishable to beneficiaries.

It is important to remember that retirees who choose to continue with their employer-sponsored drug coverage will always be able to enroll in the Medicare prescription drug program at a later date, free from any late enrollment penalties, as long as their employer's drug coverage is at least as generous as the standard Medicare drug benefit.

We are seeking comments from retirees, employers, unions, and others on the best way to implement all of those options in order to reduce retiree drug costs. On June 9 and August 19, CMS held two open door forums, allowing the public to comment on this important aspect of the drug benefit. After an overview of the issues by several panel members, the bulk of the time in these meetings was devoted to public input. CMS also issued a white paper that includes an extensive discussion of these important issues for the August forum and solicited input thereon.

Providing More Comprehensive, Lower-Cost Health Plan Choices through an Enhanced Medicare Advantage Program

The MMA expands the existing options available to Medicare beneficiaries to voluntarily enroll in private health plans. Currently, about 4.7 million beneficiaries are enrolled in these plans, known as MA local plans. The key new benefit is the MMA's new regional contracting option for new MA regional plans. The proposed regulation issued by CMS would propose to implement these and other changes to the MA program. The new regional plans, which will be available in 2006, are structured as preferred provider organizations (PPOs), which have a network of doctors and hospitals that contractually agree to provide health care services at a specified rate but also allow enrollees to go outside the network for care, usually for an additional charge. PPOs are now the most popular type of coverage in the private market in the U.S. In 2002, 52 percent of Americans covered under group health insurance programs were enrolled in PPOs. This is because they provide both coordinated care that reduces beneficiary costs, and broad flexibility in choice of providers if and when beneficiaries need them. Also addressed in the proposed regulation is a new option created by the MMA that allows specialized

plans for Medicare beneficiaries who have special needs, such as the institutionalized, those with Medicaid, and individuals with severe or disabling chronic conditions.

We are working right now to make these new MA options available to all Medicare beneficiaries in 2006. Beneficiaries will receive materials each fall that outline the options available to them and their quality and cost features, and also can get sources for additional information, enabling them to make the choice best suited to their needs.

Beneficiaries Will Get More Savings

Studies show that enrollees in current Medicare+Choice/MA plans not only receive more benefits than beneficiaries who have coverage only in the traditional Medicare fee-for-service (FFS) program only, they also pay less out of their own pockets to receive these benefits. A recent published report found that out-of-pocket payments for beneficiaries in MA plans are 34 percent less than out-of-pocket payments for beneficiaries with FFS Medicare. While out-of-pocket costs (including the Medicare Part B premium) for beneficiaries with FFS with no supplemental coverage average about $2,631 per year, the average for MA enrollees in 2003 was $1,964. Thus, on average, a beneficiary could expect to save about $56 a month as an MA enrollee.[1]

The differences in spending between MA and FFS Medicare are particularly large for beneficiaries with costly chronic illnesses and predictably high medical costs. A CMS analysis of out-of-pocket costs showed that in 2004, enrollees in poor health could expect to save, on

[1] (Marsha Gold and Lori Achman, "Average Out-of-Pocket Health Care Costs for Medicare+Choice Enrollees Increase 10 Percent in 2003," Commonwealth Fund Issue Brief #667, August 2003.)

average, about $1,900 per year by enrolling in an MA plan, as compared to FFS without supplemental coverage. (Unpublished CMS data.)

Reduced out-of-pocket payments make MA plans particularly important for lower income beneficiaries who are struggling to afford up-to-date medical care. For example, beneficiaries with incomes between $10,000 and $25,000 – beneficiaries who usually do not qualify for Medicaid, and who are unlikely to have access to inexpensive retiree coverage to supplement their Medicare coverage – are relatively much more likely to enroll in MA plans. These beneficiaries comprise about one-third of all Medicare beneficiaries, but make up half of Medicare Advantage enrollees. (Based on year 2002 Medicare Current Beneficiary Survey data.) As seniors and people with disabilities struggle with rising out-of-pocket costs for their health care, it is more important than ever to make options available that enable them to lower their medical costs substantially.

Extra Benefits and Other Savings

MA plans typically cover benefits beyond the Medicare range of covered services, and do not limit services to the same extent as Medicare (for example, the majority of MA plans offer unlimited inpatient hospital days). Such extra benefits include additional preventive benefits and wellness services; disease management and care management services for beneficiaries with chronic illnesses or high medical expenses; and dental, vision, and hearing services.

In addition to expanded benefits and lower beneficiary payments for services, MA enrollees may benefit from lower Medicare premiums as well. Eleven percent of Medicare beneficiaries currently live in a county in which there is a MA plan offering rebates on the premiums

beneficiaries pay for Medicare Part B. In three counties in Florida, beneficiaries can choose a plan that has no plan premium and that offers a full reduction of the 2004 monthly Medicare Part B premium of $66.60.

MA plans begin to offer drug coverage in 2006 under Part D. With their ability to secure discounts and coordinate the drug benefit with medical services, MA plans may be able to offer more generous drug coverage and lower premiums compared to stand-alone drug plans.

The MMA has already improved the situation of the average MA beneficiary. Under the revised MA program that will begin in 2006, *all* Medicare beneficiaries will have access to these same types of savings.

Immediate MA Improvements

While many changes in the Medicare Advantage program do not take effect until January 1, 2006, some immediate increases to payments for Medicare Advantage organizations are already improving access to health plan options and reducing costs and improving benefits for Medicare beneficiaries. This increased funding will make up for years of payment updates that were behind the cost increases M+C organizations were facing, which in turn prompted many plans to drop out of the program. In addition, the new law requires these additional payments to be used to lower premiums or improve the benefit package offered by the MA plans.

As a result of these immediate changes, about 3.7 million enrollees in Medicare Advantage plans are seeing improved benefits and lower costs. Premiums dropped for 1.9 million enrollees, and 2

million enrollees had a decline in cost sharing. Many enrollees are benefiting from more than one of these changes in their health plan. In addition, the enrollment-weighted average premium for Medicare Advantage plans dropped from $42 to $31. Further, the percentage of enrollees that will receive some type of drug coverage increased from 78 percent to 80 percent. On average, improvements in the MA benefit package made possible by the MMA outweigh recent increases in the Part B premium.

Overall, 95 percent of the increased funding is being used to help beneficiaries, with:

- 31 percent being used to reduce enrollee premiums;
- 5 percent being used to reduce the amount enrollees pay for cost sharing and co-payments;
- 17 percent being used to enhance existing benefits; and,
- 42 percent of the additional funds being used to strengthen provider networks and ensuring that beneficiaries continue to have more choices of physicians, specialists, and other health care providers.

Benefits and Beneficiary Protections

MA plans must provide all Medicare-covered benefits, and as noted above, they generally provide substantial additional benefits that allow beneficiaries who enroll to lower their costs significantly. Most MA local plans currently provide limited, if any, coverage if their enrollees choose to go outside the network for non-emergency care. And they are not required to have a single deductible or catastrophic limit on enrollee out-of-pocket costs. Beneficiaries in MA regional plans will typically have lower cost-sharing when they remain in network, but they will have more coverage of care provided outside the network that is significantly more generous

than that available in most local plans today. In addition, unlike traditional FFS Medicare with its separate deductibles for Parts A and B, regional MA plans are required to have a single, unified deductible (if they feature a deductible at all), though they may waive the deductible for preventive services and other services. Regional MA plans must also feature a catastrophic limit on out-of-pocket expenditures for in-network services, and a limit for all covered services. MA plans may also offer a prescription drug plan in conjunction with the traditional benefit package.

Regions

Unlike local plans that serve individual counties and groups of counties chosen by the plan sponsor, the new regional PPOs will bid to serve an entire region, which may be a state or multi-state area. The goal of these larger regional markets is to bring more plan options to rural areas by grouping them with the urban areas that have traditionally attracted managed care plans under the Medicare+Choice program. The MA regional plans may operate in more than one region, or even nationally. Following a market survey that will be completed later this year, as well as public comment, the Secretary will establish 10 to 50 MA regions, designed to maximize plan participation and quality and cost savings for beneficiaries. All beneficiaries will have access to a choice of such plans, regardless of the region in which they live. On July 21, 2004, CMS held a public meeting in which interested parties were allowed to offer their perspectives on establishing the MA regions. The Agency is cognizant of the importance of establishing these regions in a timely manner and is working to meet the statutory deadline of January 1, 2005. We will continue our public outreach efforts as we consider how to finalize this important aspect of the rule.

Financial Incentives for Regional PPOs

Risk Corridors

To encourage the offering of regional MA plans, MMA provided for risk sharing for Part A and B health benefits to be in effect for 2006 and 2007. Risk corridors will allow the government to share in any unexpected gains or losses that the plans incur and help plans in the early years of the regional plan program while they gain experience covering the Medicare population on a regional basis. With the risk corridors, a target amount of plan spending is set to equal the total payments to plans from the government and enrollee premiums, minus the plan's administrative costs assumed in its bid. Actual costs at the end of the year are then compared to this target amount. The risk corridors are symmetrical in that the government pays plans if costs are above the target and recoups its share of the savings when costs are below the target.

The plan is fully at risk for the first 3 percent of costs above or below a target amount.
The plan and the government share 50 percent of costs/savings that are 3 to 8 percent off the target. The government pays/keeps 80 percent of the costs/savings that are more than 8 percent off the target.

Plan Entry and Retention Fund

Starting in 2007, a plan entry and retention fund will be created consisting of $10 billion in appropriated funds plus additional monies from the bidding process (half of the government's portion of the savings based on the difference between the regional plans' bids and the regional bidding benchmarks). The fund is available through 2013 and can be used several ways:

National Bonus. If a health plan enters the program nationally (by bidding to provide a MA plan in all regions), then its benchmark payment in each region is increased by 3 percent. This bonus is available for one year only, and it is not available if a national plan was available the prior year.

Regional Plan Entry Bonus. If no regional MA plans serve a given region in one year, then the Secretary may increase payments for plans in that region for the following year. The Secretary has wide discretion to set the parameters of the regional plan entry bonus.

Regional Plan Retention Bonus. If plans signal that they are going to leave a region, the Secretary may increase the benchmark in that region in an effort to keep the remaining plans and attract new bidders. Two additional conditions must be met: the exits must result in fewer than two regional organizations being available, and the MA enrollment share in the region must be less than the national MA enrollment share. The Secretary has discretion to increase the benchmark (within certain limits), and the increase can last for up to two years.

All of the above payments are subject to the overall budget constraints for the plan entry and retention fund. The Secretary and CMS actuaries must certify that there is enough money in the fund to cover the payments, and they may limit enrollment in regional plans receiving the payments to make sure enough money is available. The Secretary must also periodically report to Congress about how the plan entry and retention fund has been used and the market conditions in regions that make its use necessary.

Essential Hospitals

One of the challenges that MA plans have faced in operating in rural environments is establishing an adequate network. Beginning in 2006, regional MA plans that are unable to successfully contract with certain essential hospitals are eligible to receive limited assistance to establish an adequate network. If specific criteria are met, CMS is authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. These funds are limited to $25 million in 2006, with inflationary updates in succeeding years.

An essential hospital means a general acute care hospital that CMS determines the MA regional plan must have under contract in order to meet access requirements. The determination of essential hospital status is only conferred after appropriate application to us by an MA organization offering an MA regional plan. Finally, in order to qualify for the additional payment, the essential hospital must demonstrate to our satisfaction that the amounts normally payable are less than the hospital's costs for providing services to MA regional plan enrollees. In addition, there is a minimum amount to be paid by the MA plan and a maximum total payment, including the Medicare payment to the essential hospital.

The intent of the additional payment to essential hospitals is to facilitate an MA regional plan's ability to meet network adequacy requirements across large geographic areas—an MA region. Such an essential hospital would become part of the contracted network of providers of the MA regional plan and in-network enrollee cost-sharing rules would apply. CMS anticipates this provision to be particularly helpful to rural beneficiaries. The proposed regulation seeks

comments on other approaches within our statutory authority to support effective access for rural beneficiaries in all parts of a PPO region.

Improved Quality and Patient Safety

Under the MMA, CMS is moving to increase patient safety and quality of care through a number of initiatives. The focus is on obtaining better results for the dollars we spend. To accomplish this, among other things, the statute requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for electronic prescribing standards. E-prescribing is a proven method of reducing medication errors and CMS looks forward to working on this important effort. NCVHS has consulted with physicians, hospitals, pharmacists and pharmacies, pharmacy benefits managers (PBMs), State boards of pharmacy and medicine, Federal agencies and other electronic prescribing experts in its work to develop uniform standards. The law also requires a pilot project once the Secretary has adopted or announced the initial standards. The pilot will run from January 2006 through December of that year, and it will be completed prior to the promulgation of the final standards. We expect that NCVHS will shortly be communicating its recommendations to the Secretary.

Medication therapy management services are also called for under MMA. The statute allows a broad range of services under this provision. The purpose of medication therapy management is to provide services, distinct from dispensing drugs, that optimize therapeutic outcomes for targeted beneficiaries.

Medication therapy management may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding--through beneficiary education counseling, and other means--that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, other compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision a broad range of simple to complex services falling under the heading of medication therapy management services. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We expect that these services will help increase the effectiveness of medications used by beneficiaries and reduce the number of adverse events associated with drug interactions or reactions.

CMS has also begun an exciting program designed to improve care for beneficiaries with chronic conditions. Under Section 721 of the MMA, CMS will contract with a number of disease

management programs to provide services to beneficiaries with a select range of chronic conditions. These disease management programs will use a broad range of proven and promising techniques to help beneficiaries comply with physician treatment plans, drug regimens and lifestyle changes in order to reduce the number of hospitalizations and acute incidents that they experience. The disease management organizations' payments will depend entirely on their ability to prove reduced costs to the program. The statute provides for a broader application of the Chronic Care Improvement Program. In addition, all MA plans will be required to use disease management techniques to help beneficiaries with chronic conditions and their physicians better manage their health. The increased quality of information that these disease management programs will provide to patients and their physicians, along with their reliance on proven standards of care could result in Medicare beneficiaries receiving higher quality, more effective care at lower costs overall.

Through clear, consistent and integrated communications and effective partnerships, the Quality Improvement Organizations (QIOs) are continuing to work with providers, stakeholders, purchasers/payers, and the media to help stimulate widespread change in attitudes and behavior with regards to the importance of ongoing quality and safety improvement in health care. There is tremendous opportunity for improving quality and safety in health care for seniors, particularly involving prescription drugs. For example, a recent study of nearly 400 hospitalized elderly patients reported in the Annals of Pharmacotherapy found that nearly 92 percent of patients had received a medically inappropriate prescription.[2]

[2] Hanlon, Joseph T., et. al., "Inappropriate Medication Use Among Frail Elderly Patients," in *The Annals of Pharmacotherapy*, vol. 38, no. 1, pp. 9-14.

Specifically for the Part D drug plan, the QIO's, working with the Agency, will begin work with PDP, MA-PD plans, and fallback plans, (referred to as drug plans), and providers to help promote higher quality care for beneficiaries enrolled in these plans. QIOs will develop quality improvement projects that measure performance of the drug plans and providers with whom they work. Performance measures will be organized according to the Institute of Medicine's (IOM) six identified criteria for quality: *Safe, Effective, Patient centered, Timely, Efficient, and Equitable*.

CMS will monitor the QIOs' work with these plans and their ability to disseminate important quality improvement information learned in their efforts. The QIOs will also identify and offer technical assistance to all drug plans that serve beneficiaries within their state to implement quality improvement programs.

Timely Implementation

Implementing all of these new benefits and programs involves a tremendous amount of work. Because Medicare has never before offered outpatient prescription drug coverage, CMS must engage in a new line of business to establish these benefits. To implement regulations for these programs CMS must propose regulations to the public, accept and respond to comments, and issue the final version. CMS is hiring a large number of new people with specific knowledge and skills (e.g., administration of pharmacy benefit programs and employer benefits), preparing to build computer systems, negotiate and execute complex contracts, institute monitoring mechanisms, and expand our current beneficiary education and support program. To help us in hiring the right people, CMS is participating in an innovative public-private effort with several

leading human resources firms, including Monster Government Solutions, ePredix, CPS Human Resource Services, AIRS, Brainbench, and Korn/Ferry International. These entities will be donating their services to analyze CMS' hiring process and make suggestions for improving things so that the Agency can employ the most qualified persons in a timely fashion. The 2006 deadline for all of this to happen is very ambitious and CMS has been diligently laying the groundwork for that opening day since the moment the legislation was signed.

The Medicare Approved Prescription Drug Discount Card – A Bridge to the New Benefit

While working on the myriad of tasks required to implement the new drug benefit and improve the MA program, CMS has already implemented an important program to offer some immediate relief to seniors with high drug costs. The Medicare Approved Prescription Drug Discount Card program, announced only a few days after President Bush signed the MMA, is now offering concrete assistance to Medicare beneficiaries with little or no drug coverage.

To date, well over 4 million beneficiaries have enrolled in the drug card program. The beneficiaries who are receiving real savings now represent well over 50 percent of the 7.4 million seniors who CMS estimated would sign up for the card by December of 2005.

Medicare beneficiaries began signing up for drug cards on May 3, with discounts beginning June 1, 2004. Since that time there has been steady growth in beneficiaries signing up for the card with drug card sponsors now receiving an average of well over ten thousand enrollees every day. As of September 2, more than 4.3 million beneficiaries have enrolled in a card program. Well over 1 million of those beneficiaries are receiving the $600 low-income credit. Approximately

2.4 million beneficiaries were automatically enrolled in a card by their health plans and nearly 350,000 were auto-enrolled through their state pharmacy assistance program (SPAP), with an additional 13,000 being sent pre-filled applications by their SPAP.

A recent Kaiser Family Foundation study reported that top Medicare drug cards provide savings as compared to retail of between 19 and 24 percent for urban retail prices, 17 to 22 percent for rural retail, and 27-32 percent urban mail order.[3] A study released in July by The Lewin Group analyzing 150 drugs most frequently used by seniors found that individuals participating in the Medicare drug discount card program beginning in the summer of 2004 will save an average of $1,247 on their prescription drug purchases before the program concludes at the end of next year.[4] A June study by the American Enterprise Institute found that the Medicare approved drug discount cards offered discounts of 8–13 percent off of brand name retail prices and 15-23 percent on mail order brand name drugs.[5] A study by the Consumers Union found that Medicare approved drug discount cards available in California consistently provided drug prices *lower* than those available under the Medi-Cal program. Medi-Cal prices are already 20 percent lower than those typically available in a retail setting and the study concluded that prices under the card

[3] *Medicare Drug Discount Cards: A Work in Progress*, Prepared for the Henry J. Kaiser Family Foundation by Health Policy Alternatives, Inc. Available at: http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

[4] *Assessment of Beneficiary Savings in the Medicare Drug Discount Card Program*, Prepared for the Healthcare Leadership Council by Jennifer Bryant, John Corea, and Allison Sydlaske of The Lewin Group. Available at: http://www.lewin.com/NR/rdonlyres/e3ojwukgg5tthdntqdykfairad7nn676zrmeafuqoxjpwaonge6fgl3dn3p7mygqytdcndur2nfm5m/LewinHLCStudy.pdf

[5] *Private Discounts, Public Subsidies: How the Medicare Prescription Drug Discount Card Really Works*, Prepared by the American Enterprise Institute, Joseph Antos and Ximena Pinell. Available at: http://www.aei.org/docLib/20040616_book779text.pdf

program could be reduced by as much as 10 percent beyond Medi-Cal's rates.[6] The results of these private studies all compare well with CMS studies, which have shown similar savings.

Beneficiaries should know, that signing up is as simple as calling 1-800-MEDICARE with the information on their prescriptions, their preferred pharmacy, and their annual income. The customer service representatives at our call centers can walk them through their drug card options and the process of enrolling in an appropriate drug card in just a few minutes. The person can quickly enroll in a card and begin realizing savings on the medications they need.

Education and Outreach

CMS is aware that one of the greatest challenges will be to accurately inform beneficiaries about these new options and assist them in taking advantage of these services. CMS has taken many steps to increase beneficiary assistance and seeks comments on how to further improve our ability to help beneficiaries get the personalized, one-on-one assistance they need to get the most out of Medicare's expanded benefits and out of our increasingly modern, but increasingly complex, health care system. These activities will build on our broad experience and success using the National Medicare & You Education Program begun in response to the Balance Budget Act of 1997. We will employ the comprehensive elements of this Program to ensure that people with Medicare know about these new benefits and choices, and understand how to make informed decisions to enroll in the health plans and the prescription drug plans that offer these benefits. Elements of this Education Program and examples of consumer products and assistance include:

[6] *Medicare Discount Drug Card Savings in California: Technical Summary*, Prepared by Consumers Union for California Healthcare Foundation. Available at: http://www.chcf.org/documents/insurance/MedicareDiscountDrugCardSavings.pdf

- Publications for People with Medicare

  CMS intends to continue and enhance the use of targeted publications and informational mailings to help people with Medicare understand the new benefits and how to get the most out of these benefits. These mailings and related publications will also be available online at www.medicare.gov. Numerous mailings have already been sent to people with Medicare to help them learn about, and enroll in, the Medicare-approved drug discount cards and the formal drug benefit coming in 2006.

- Medicare & You Handbook

  Additionally, each fall CMS mails *Medicare & You* handbooks for the next plan year to beneficiaries and stakeholders. Handbooks are offered in English and Spanish, and are also available in Braille and large print. CMS also mails *Medicare & You* to new enrollees throughout the year on a monthly basis.

- 1-800-MEDICARE Toll-Free Telephone Services

  CMS undertook recent enhancements at 1-800-MEDICARE so that people with Medicare can get additional support in identifying the best drug plans and health plan options for their needs. CMS has increased the number of customer service representatives (CSRs) from several hundred to 3,000 and expects to maintain this number of trained CSRs to handle the unprecedented number of callers in a timely and effective manner. CMS has added voice messages to help callers be better prepared when they reach a customer service representative, further reducing call waiting and call handling time.

- www.medicare.gov

  The most significant recent enhancement to the Medicare web site is the release of information on the new Medicare-approved drug discount cards. The Prescription Drug

and Other Assistance Programs (PDAP) section of www.medicare.gov provides information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. Enhancements and updates to the site will continue frequently to ensure users get the accurate information they need, easily and in a timely fashion.

- National Publicity Campaign

  The CMS national multi-media campaign utilizes television, radio, print, and Internet advertising, to inform and motivate people with Medicare and their caregivers to call 1-800-MEDICARE, visit www.medicare.gov, and refer to the *Medicare & You* Handbook for answers to their Medicare questions. For example, the last week of April 2004, CMS initiated a new TV and print ad campaign to introduce the Medicare-approved drug discount cards, and launched new advertising in late August to further encourage enrollment in the cards.

- Public Private Partnership

  CMS currently partners with more than 140 organizations and groups on education and outreach efforts. We have taken steps to expand the partnership base to provide stronger entrée into community and faith-based service organizations, health information providers, and aging outreach centers – groups that work with Medicare beneficiaries who are most in need.

- Community-Based Outreach

  CMS also supports non-profit organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach. We recently announced the

availability of $4.6 million in grants and contracts to community-based organizations, local coalitions, and national organizations to help people with Medicare learn about the $600 in transitional assistance money available through the Medicare-approved drug discount cards. CMS continuously looks for the most effective ways to work with State Health Insurance and Assistance Programs (SHIPs), as well as private organizations, to help further improve our personalized outreach and support.

- Regional Education about Choices in Health (REACH)

  CMS' ten Regional Offices (ROs) manage the Regional Education about Choices in Health (REACH) program to cultivate community-based partnerships with organizations that use existing outlets to conduct education activities for populations with barriers caused by differences in language, literacy, location, low income and/or culture. Many REACH partners serve beneficiaries who prefer and need in-person information and assistance in familiar, community settings.

- State Health Insurance Assistance Programs – SHIPs

  For beneficiaries with unique and complex issues and who require face-to-face personalized assistance, CMS has also enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). CMS recently announced that HHS will award $21.1 million this year, and another $31.7 million next year, to the SHIPs, reflecting the increased emphasis on one-on-one advice and counseling for people with Medicare. The SHIPs are an essential resource in helping beneficiaries learn about the changes to Medicare and will be able to use the additional funds to equip local organizations with the tools needed to answer beneficiaries' questions.

- Training for Information Intermediaries

CMS has developed a national training program to educate and train CMS staff, partners, and information intermediaries who are responsible for educating people with Medicare about their health care choices, benefits, rights and protections. Training is made available in a variety of different ways including web-based, face-to-face and on CD-ROM.

- Consumer Research and Performance Measurement

  To help ensure that all of these education and outreach efforts effectively reach people with Medicare with relevant and understandable information, CMS conducts consumer research. This research includes both formative research to determine what information different segments of our population want and how to convey it, and testing of publications, material for the website and media messages and strategies.

Program Assessment

A fundamental building block of the National Medicare & You Education Program is a multifaceted approach to assess the overall strategy of educating beneficiaries about Medicare. These performance measurement activities identify what is working well and what needs to be improved in each of the activities used to communicate information about Medicare. The performance measurement system addresses all elements of NMEP. The assessment information is used for continuous quality improvement of each element as well as to improve how well the different elements work together. The channel-specific measurements cover: print materials; toll-free telephone services (1-800-MEDICARE); the internet (www.medicare.gov); Regional Education about Choices in Health (REACH); National Alliance Network; national training and support for information givers; and enhanced beneficiary counseling from the State Health

Insurance Assistance Programs (SHIP). We have also conducted case studies in six communities to study the evolution of the National Medicare & You Education Program in these communities. The case studies add to our other performance measurement activities by providing information about how all of the elements of the education program work together at the local level.

Summary

Beginning in 2006, Medicare beneficiaries will have access to higher quality, more affordable, more comprehensive and integrated modern health care. They will have choices about how they obtain those benefits, and their market power will be used on their behalf to lower the prices they pay. CMS looks forward to working with the Congress in implementing these important new programs and we emphasize, again, our strong desire for public participation and comment in this process. I thank the Committee for its invitation to come here today to discuss these, the most important changes in Medicare's history, and look forward to any questions you may have.

CMS Progress in Completing Medicare Modernization Act
Provisions with Effective Dates
From Enactment, December 8, 2003, through August 31, 2004