Ms. PELOSI. Mr. Speaker, the Democratic plan does just that. This Republican bill, I repeat, is not guaranteed. It is not affordable. It is not a defined prescription drug benefit under Medicare that our seniors want and deserve. The Republican plan is a plan to end Medicare. I urge my colleagues to reject this raw deal for America's seniors and vote no on the Republican bill and yes on the very excellent Democratic proposal.

Mr. TAUZIN. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, when we test the arguments made on the floor of the House on a major piece of legislation such as this, it is important to test the credibility of those arguments. The best way to test that credibility is to first tell Members a fairy tale.

Once upon a time Bill Clinton proposed Medicare prescription drug coverage for America. Once upon a time my Democratic friends, the gentleman from California (Mr. STARK), the gentleman from Michigan (Mr. DINGELL), the gentleman from California (Mr. WAXMAN), the gentleman from New York (Mr. RANGEL), the gentleman from Ohio (Mr. BROWN), and many others introduced a bill, H.R. 1465.

Once upon a time Democrats recommended a bill with a $200 deductible, 80 percent cost sharing by the government up to $1,700 of drug expenses, a donut hole, and then $3,000 out-of-pocket catastrophic coverage with no defined premium. And guess what, once upon a time their bill provided that the benefits would be provided through a PBM. Members might ask how would the PBM be selected: By competitive bidding.

Members might further ask how would the contracts be awarded under this privatization of Medicare, and the answer in a fairy tale world would be shared risk capitation of performance. But the truth is this is not a fairy tale. It happens to be the truth. That was the Democratic proposal on Medicare prescription drugs. But tonight Democrats have come to the floor one after the other and criticized this plan because it contained many of those same features. Different, however, in some respects because this plan provides better coverage for seniors on the bottom. In fact, while some of my friends came to the floor and called this a sad day and said how sorry they were for the citizens of California, this bill we proposed would put 14 million California senior citizens in plans that would cost them no premiums, no deductibles, free entry for drugs in California for 14 million senior citizens, half a million in Indiana, half a million in Ohio, half a million in Pennsylvania, almost a million in Texas, and so on and so forth, free drug coverage under this plan, and yet the fantasy plan offered by the Clinton administration just a few years ago containing many of the same elements is somehow forgotten. It is somehow put away in a closet. It is somehow not to be remembered, and this plan is to be attacked. When we test credibility of arguments on the floor of the House, test them against the reality of the plan offered by the Democrats and the reality of the plan offered today.

I want to thank the gentleman from Michigan (Mr. DINGELL) for the courtesies and the respect and the statesmanship he has always shown me in debates in committee and on the floor of House. The gentleman is a dear friend. I wish I could say that about all Members all the time. But let me say something, I am offended that anyone would come to this floor and accuse anyone in this House of wanting to get old people. Do Members think for a second they love their moms and dads any more than we love ours?

I ask the gentleman from California (Mr. STARK), do you really believe that? God bless them. That is the sort of unstatesmanship that should never enter the halls of this House. There is nobody in this House that loves their mother more than I love my mother. I challenge Members on that.

She is a three-time cancer survivor, she is 84 years old, and she won first place at the Senior Olympics this year in shotput, and if you give her trouble, I will sic her on you.

There are Members who have come to the floor and said seniors cannot understand choice. Let me tell Members something, I grew up in a poverty family. My mom and dad never earned above poverty. They made hard choices all their life for us. They sent three out of their four children to college. They fed and clothed us and gave us a great education and a chance for me to come to Congress. I love that woman and I loved my dad as long as I had him. How dare anyone suggest otherwise. We love our parents and grandparents the same.

We differ on how to structure this program today. Apparently we did not a few years ago, but we do now. That is a legitimate debate and that is worthy of this House, but to suggest that any of us care less about old people, to suggest that any of us love those citizens who gave so much and made those hard choices for us any less than we do is a shame. My parents made hard choices. My mother knows how to make hard choices. She is 84 years old, and she won first place at the Senior Olympics this year in shotput, and if you give her trouble, I will sic her on you.

There is nobody in this House that loves their mother more than I love my mother. I challenge Members on that. She is a three-time cancer survivor, she is 84 years old, and she won first place at the Senior Olympics this year in shotput, and if you give her trouble, I will sic her on you.
credibly important Medicare program, including for Medicare beneficiaries and put an end to evaluation by providing a prescription drug benefit. Today we have an excellent opportunity to address this tragic situation and put an end to the exploding costs of prescription drugs. As such, I want to preserve what's good about Medicare, not destroy it by making extravagant promises for political gain.

The enormous extra spending under this bill will be far more than projected. Because today's Medicare is a huge price control system, many doctors already refuse to see Medicare patients. In just a few years this will make it worse, including price controls that will destroy the incentives for companies to create new medicines.

What should we be doing?

Since 76 percent of seniors already have drug coverage, we could focus on helping those who don't. But this bill undoes the coverage that we have created, and puts them in a confusing new medical experiment.

We should be stabilizing Medicare, so it can keep the promises already made, not making new promises that we don't have the money to keep.

We should address the reasons why drug prices and healthcare costs are so high. By banning re-imported drugs, we're forcing Americans to subsidize far-lower drug prices in other countries. We should change our policies so Americans only pay the lower world price, not a higher price.

We should end the 130,000 pages of federal regulations that have driven the costs of medicine and healthcare through the roof. On average, for every hour they spend with a patient, doctors and nurses spend another half-hour doing paper work.

We should stress personal responsibility in healthcare, just as we did in welfare reform, so government resources are focused on those who cannot care for themselves, not on those who can.

Bit-by-bit, Congress is undoing the principles of welfare reform, and undercutting basic American principles in the process. Both political parties are making extravagant promises today, trying to outbid each other to win votes. Unfortunately, they are bidding with taxpayers' own money, and our children's hopes will be crushed by the bills they will inherit.

Mr. UDALL of New Mexico. Mr. Speaker, for far too long, as I traveled around the state of New Mexico, seniors have told me their heart-breaking stories of being forced to choose between purchasing their medicine and purchasing groceries as a result of the exploding costs of prescription drugs. Today we have an excellent opportunity to address this tragic situation by providing a prescription drug benefit for Medicare beneficiaries and put an end to the outrageous dilemma facing our seniors throughout this country. In addition, we have an historic opportunity to modernize the incredibly important Medicare program, including updating formulas for our health care pro-viders in rural areas—an issue that is of particular importance to my constituents and me.

Thankfully, H.R. 1 does address the latter concern, but unfortunately falls far short on the critically important issue of prescription drug coverage. The prescription drug benefit proposed in H.R. 1 would be a first step toward privatizing one of the most successful government programs in history, leaves seniors at the mercy of insurance companies, forces seniors into HMOs, has an incredible gap in coverage, and does nothing to control the exploding costs of prescription drugs. As such, I cannot vote in support of H.R. 1.

Under this bill, seniors and disabled Medicare beneficiaries can obtain their prescription drug coverage only from HMOs and private insurance companies. Given the history of HMOs and other private health plans in rural areas, I have serious concerns about this approach. In fact, in 1997 in the state of New Mexico, HMOs dropped approximately 18,000 individuals because of rising costs. These individuals were left with nowhere to turn.

Mr. Speaker, H.R. 1 would put beneficiaries at a similar risk by relying on the ineffective purchasing power of Medicare's 40 million beneficiaries. This will lead to higher prices and healthcare costs are so high. By banning re-imported drugs, we're forcing Americans to subsidize far-lower drug prices in other countries.

Furthermore, further contributing to this risk is the fact that there is no fallback option to allow traditional Medicare beneficiaries to purchase prescription drugs from their independent providers. Because much of my district is rural, this legislation would put the seniors in my district at particular risk. I cannot support this.

This is greatly disappointing to me given the several major rural healthcare provisions that are included in this legislation. The labor share revision, the geographic physician payment adjustment, equalizing the Medicare disproportionate share payments, increasing home health services furnished in rural areas, critical access hospital improvements—these are all incredibly important provisions that I strongly supported in order to help strengthen the healthcare system in rural areas. I cannot, however, vote in support of H.R. 1 with the extreme, flawed prescription drug benefit included with these strong rural health provisions.

Mr. Speaker, I strongly support adding a voluntary prescription drug benefit to Medicare. I strongly believe that we must take action to provide relief for our nation's seniors. I simply do not believe, however, that H.R. 1 is the most effective way to do so. Tonight I will be voting in support of the substitute being offered by Mr. Rangel and Mr. Dingell.

In addition to including stronger rural provisions than those included in the Majority's bill, the substitute includes a guaranteed benefit of a $25 premium, a $100 deductible, 20% co-insurance, and a $2,000 catastrophic protection. The substitute also allows for lower drug prices by granting the Secretary of Health and Human Services the authority to use the collective purchasing power of Medicare's 40 million beneficiaries to negotiate lower drug prices. Also, the substitute grants access to generic drugs, and allows the safe re-importation of pharmaceuticals, providing further tools to seniors for gaining access to cheaper prescription drugs.

Perhaps most importantly, the substitute will not force seniors to leave traditional Medicare to get drug coverage. Nor will they be forced to join a private insurance plan that will restrict access to needed drugs, deny coverage for the medicine their doctor prescribes, or force them to change pharmacies.

Mr. Speaker, our seniors deserve a real prescription drug benefit, not the flawed benefit the Majority wants to force seniors to choose between medications and groceries any longer, and, unfortunately, H.R. 1 will not adequately address this situation.

Finally, I urge my colleagues to support H.R. 1, the Medicare Modernization and Prescription Drug Act. I want to begin by appreciating the incredible time and energy that my colleague, NANCY JOHNSON, has put into crafting what I consider to be a good product, and thank her for her efforts.

When Medicare was created in 1965, the program's principal purpose was to help seniors pay for their hospital costs. Since that time, Medicare has not kept pace with how health care is delivered. Today, we are bringing this program into the 21st Century by including coverage for prescription drugs.

Our seniors need and deserve prescription drug coverage under Medicare. This legislation will give them tremendous assistance. After a $250 deductible, seniors will get 80% of their first $2,000 paid for by the program, catastrophic protection from any cost over $3,700, and discount on all their pharmaceutical costs from an Rx Drug Discount Card. The card will save beneficiaries between 10 and 25 percent on every purchase.

I believe this bill takes a positive step towards injecting competition into Medicare, but I regret we did not go further in reforming the program to ensure its solvency for future generations.

I also believe anything free, even health care, is over-utilized. I support the House proposal to add a small co-payment to home health care and to index Part B deductibles to inflation, and I support the Senate proposal to have seniors pay a portion of their catastrophic costs. This way, seniors have a greater incentive to get care because they need it, not just because it is offered.

Finally, we must be concerned with what this program will ultimately cost. It could go well over the $400 billion we budgeted and accelerate the program's financial demise if we are not vigilant.

There is a lot to like in the bill we hope to pass tonight, and the Senate has already passed a plan I can support. My hope is the House and Senate conference will draft a final bill that takes the best approaches from each chamber and that we can send to the President a Medicare prescription drug bill supported by both sides of the aisle. I urge my colleagues to support H.R. 1.

Mr. DAVIS of Illinois. Mr. Speaker, late last night, the House Rules Committee sent a terrible message to our Nation's seniors and hospitals. Two amendments I proposed were not allowed to pass onto the House floor. The first amendment would have stricken the language regarding the “market basket” index. Under the current bill hospitals would lose $12 billion over the next ten years. My amendment would protect the hospital funding level so that hospitals would not be forced to make difficult cuts in services and jeopardize patient care.
My second amendment would have assured that the prescription drug benefits we members of Congress enjoy would be comparable to those of Medicare beneficiaries. My colleagues in the Senate passed such an amendment, but the Members of the House Rules Committee seem reluctant to subject themselves to the same benefits they would give our Nation’s seniors. They have sent the clear message that these benefits are not good enough for them, the relatively young and healthy, but are adequate for our Nation’s seniors and disabled persons.

One thing Congress has proven is that the Democratic process is not working. Not only are the voices of America’s seniors not being heard, but neither are those of Members of Congress. As we go home to celebrate our Nation’s independence, we will have to explain to those seniors that yes, a prescription drug bill passed, but it will not benefit them. It will not benefit middle America, it will not benefit the poor, it will not benefit those who are already struggling to buy their prescription drugs. It will only benefit those who can currently afford their drug—afford to pay for more hospital services, and afford to pass this bill. Mr. Speaker, I oppose this rule and I oppose the underlying bill.

Mr. HOLT. Mr. Speaker, for forty years, the federal government has kept a promise to our nation. That promise is called Medicare, and it means that every senior will receive affordable, reliable health care in their later years.

Four years ago, I came to this Congress having made a promise to the seniors in my Congres­sional District. I told them that I would work to bring Medicare into the twenty-first century by including coverage for prescription drugs. Cov­erage that, like the original Medicare program, is comprehensive, voluntary, universal, and reliable—without hampering the innovation that has brought us so many miraculous drugs over the past few decades.

Today I am voting to keep that promise by opposing a bill that would undermine the Medicare program itself. H.R. 1 purports to offer seniors coverage for the prescription drugs they rely on every day. Unfortunately, it falls far short when held up to the spirit and practice of Medicare.

The most distressing aspect of this bill, to me, to my constituents, and to the AARP, is that it takes the entire Medicare program down a short road to privatization. By the year 2010, Medicare would be converted to a voucher program with competition between managed care plans and traditional fee-for-service—only the deck would be stacked against the traditional plans. Seniors would find themselves forced into managed care pro­grams like the Medicare-Choice programs that have failed so miserably in central New Jersey.

Rather than giving seniors what they want and deserve—a reliable, affordable drug ben­efit under Medicare, this provision, glibly called “premium support,” will establish the pro­gram and lead to substantially higher costs for seniors who want to stay in traditional Medi­care.

Yet another element of confusion comes from the bizarre “donut hole” in coverage under this bill. Seniors would find themselves paying 20 percent of drug costs up to $2000 in drug costs—then having no coverage until they reach $4900 in drug costs, when a cata­
strophic cap finally kicks in. Not only is this ex­tremely convoluted, it ends up leaving seniors with a very paltry benefit. A beneficiary with $5000 in annual drug costs would pay nearly $4000 out of their own pocket!

This may be alarming to seniors who cur­rently have no drug coverage. There are mil­lions out there, however, who may think this debate won’t really affect them because they already have coverage under their company’s retiree benefit packages. I want them to know that the Republicans have quite a surprise in store for them.

If this bill passes, nearly one-third of em­ployers currently offering retiree drug bene­fits—covering 11 million seniors—would drop that coverage. Retiree benefits would not count towards the beneficiary’s out-of-pocket limit, making it almost impossible for seniors with retiree coverage to ever reach the cata­strophic cap. So the bill actually discriminates against seniors with existing coverage and will have the practical effect of employers ending their benefit. This provision makes no sense—why on earth do we want to have less private sector drug coverage?

While I am disappointed with the underlying bill, I am pleased to see that the Rules Com­mittee made the Dingell-Rangel substitute bill in order. This legislation would go a long way to fulfilling the promise I mentioned—it would provide a reliable, stable benefit under Medi­care. Beneficiaries know exactly what they would pay—20 percent of drug costs up to $2000 in out-of-pocket costs with a defined premium of $25 per month and a defined de­ductible of $100.

Tonight by passing H.R. 1 we could be bringing about the end of a program that served seniors so well. Instead, we should pass the Dingell-Rangel substitute. That is what seniors need and deserve.

Ms. CHRISTENSEN. Mr. Speaker, I rise in strong opposition to the Republican prescrip­tion drug bill, and in favor of the Dingell/Ran­gel Substitute.

We have been talking about a Medicare drug benefit for at least as long as I have been here—seven years. It is time to deliver. We owe it to those seniors who need it because their lives depend on it.

I have lobbied for the day when all people living in this country have reliable, comprehen­sive insurance coverage. Today we can bring this within the reach of every person on Medi­care.

About 25 percent of my patients when I was in practice were on Medicare. Many could not get a full month’s supply of medication be­cause they could not afford it on their fixed in­come. We would try to make it up with sam­ples, but not have been as effective but was within their price range, and better than nothing, and with a lot of prayer. It is probably the latter which got them through.

The bill, H.R. 1, as usual comes with a good sounding name, but true to form it does noth­ing good at all. Instead, it misleads the older Americans who have been looking to us for help.

We need a benefit that is truly a benefit—one that is affordable and fair—through a pro­gram they know, have used all along and trust;

It needs to be available to all beneficiaries without having to navigate through the maze of man­aged care.

And we need to make it reliable—no holes to fall through when they might need it most; No dropping them like hot potatoes like hap­pened with Medicare + choice.

Finally tonight, we have such a bill in the Democratic, Rangel/Dingell substitute.

In this bill, there are no slight of hands. What you see is what you get.

And our plan strengthens Medicare, while the Republican plan would slowly kill it.

No tricky numbers, no fancy words, just a simple Medicare prescription drug plan. That is what the senior and disabled citizens have been asking for and that is what they deserve. It is what God-willing; I hope I would have when I am on Medicare.

What we are doing for Medicare beneficiaries, who have played an important role in making this coun­try what it is, and paved the way for all of us, and those who have special needs, what I want for my family and myself.

The Democratic substitute, developed under the leadership of John Dingell and Charles Ringell, is the only bill before either body, which honors our seniors’ gift to all of us.

Let us do the right thing. Reject the Repub­lican bill and pass the Democratic substitute. Ms. HINOJOSA. Mr. Speaker, I rise today in opposition to the Republican prescription drug bill. For years, our seniors have been begging for help to obtain affordable prescription drugs. Unfortunately, however, the bill before us today gives relief not to our vulnerable seniors, but to the large drug companies.

It forces Medicare patients into multiple pri­vate drug plans and out of Medicare. It under­cuts seniors’ collective purchasing power and enables the drug industry to maintain its unjustifiably high prices.

Those who live in rural and undeserved areas will find themselves without any cov­erage because insurance companies will not be required to serve them and are given no incen­tives to provide coverage. Because of a large coverage gap, over half of all seniors will still be required to pay thousands of dollars a year for prescription drugs as well as the pro­gram premiums.

Hidden in this bill is also another provision that will change the way cancer patients are treated and subject them to delays and re­duced access to care.

By contrast, the Democratic plan offered by Mr. RANGEL would provide voluntary prescrip­tion drug coverage for all Medicare bene­ficiaries. The plan curbs drug costs by allow­ing this Secretary to use the collective bar­gaining power of Medicare’s 40 million bene­ficiaries to negotiate lower drug prices.

I urge my colleagues to oppose the sham Republican proposal and support the Rangel substitute that provides real benefit to our Na­tion’s seniors.

Ms. MILLENDER-MCDONALD. Mr. Speaker, I stand here with my colleagues tonight to talk about the need for affordable prescription drug coverage for women. Because women suffer more from chronic illnesses requiring medica­tion than men do, they pay more out of pock­ets for their medications though their financial re­sources are often limited.

The proposed House bill would fail to offer meaningful prescription drug coverage to the millions of low-income women with incomes below the 135 percent poverty level who do not have retiree health benefits. Also, the House bill would raise the amount of co-payments that our country’s poorest women Medicare beneficiaries are forced to pay.
Unlike the House bill, the Senate proposal, while not perfect, would be far more helpful to elderly women who range from 74 to 160 percent of the poverty level. Under the House bill, the out-of-pocket costs paid by elderly women will still make it difficult for them to get their much-needed prescriptions. One sentence in the House bill is shocking. Old struggling women seniors who are in greatest need of assistance will receive up to 40 percent fewer prescriptions than those seniors who are able to afford private insurance. Our elderly women, who are among our most vulnerable citizens, deserve far better treatment than this. It is critical that as Members of Congress, we help women and all seniors by expanding Medicare to offer a prescription drug benefit that is universal, affordable, dependable, and voluntary. We can do no less than to offer elderly women access to adequate healthcare that they can afford and easily access.

Our Republican colleagues are offering a plan that gives no real guarantees or assistance to those who need quality prescription drug coverage the most.

Furthermore, the House plan would force seniors to purchase their own private insurance, a tactic that will benefit insurance companies, and not seniors. This is a catastrophe we can avoid if we craft the right policy to benefit our elderly now. When it come to our elderly women, we know that:

Women make up 58 percent of the Medicare population at age 65, and 71 percent of the Medicare population at age 85.

Overall, elderly women have more chronic health problems than elderly men do.

On average, women live another 19 years after retirement, while men typically live another 15 years after retiring.

Due to the obstacles they face in enrolling, almost half of elderly women with incomes under the poverty limit are not enrolled in Medicare.

As compared to married women, widows are four times as likely, and divorced or single women are five times as likely to live in poverty upon retirement.

Many elderly women survive on fixed incomes. Over half of the older women age 65 and above earn less than $10,000 annually, and three out of four earn under $15,000 yearly. In contrast to elderly men, older women age 65 and above earned $14,820 as compared to $26,543 for men in the same age group.

Once retired, women earn less than men because:

Women tend to save less than men do throughout their lives which decreases their lifetime earnings.

Elderly women usually have smaller Social Security benefits and pension incomes than men do.

Minority women are much more likely to earn less and live in poverty than are White women. Even when they have similar educational backgrounds, minority women tend to earn less and own fewer assets.

Yet another fact is, the older and poorer a woman is, the higher her out-of-pocket health care costs will be, and the more help an elderly woman requires, the less likely she is to receive assistance. As a nation, though we are facing a great economic crisis, we are still obligated to provide assistance to our most needy citizens. Let us take good care of our elderly women and men by not enacting a prescription drug policy that will force them to choose between either buying food or paying for necessary medication.

Mr. COSTELLO. Mr. Speaker, I rise in strong opposition to H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003. In recent discussions in my district that I would not support legislation that would fundamentally change the nature of Medicare and provide a prescription drug benefit that relies solely on insurance companies. I am opposing the bill because it does just that.

Medicare has been a success because it provides guaranteed coverage for all elderly and disabled Americans. H.R. 1 would end Medicare as we know it and may particularly harm rural areas that depend on the traditional Medicare program. Beginning in 2010, H.R. 1 would force the Medicare fee-for-service program for doctors and hospitals visits to compete with private insurance plans. People who wanted to remain in traditional Medicare would find their premiums going up as other beneficiaries opted for bargain private insurance coverage. Their Medicare coverage would essentially be forced out of the traditional fee-for-service program and into some form of managed care.

In addition, the Republican approach does not guarantee the same benefits for all seniors. Seniors who live in rural areas and doctors negotiate lucrative contracts with managed care plans would have to pay more; seniors with higher incomes would have to pay more; seniors in rural areas would have fewer choices of doctors and pharmacies; and seniors with low incomes but with assets such as a savings account might get nothing at all. These provisions violate the central promise of Medicare: to provide a consistent, guaranteed benefit that allows everyone, no matter where they live, how much they have, or how sick they are, access to quality medical care.

Finally, H.R. 1 is flawed because it offers seniors an inadequate prescription drug benefit. I support a voluntary prescription drug benefit paid for by Medicare. I am committed to providing a comprehensive benefit that is all-inclusive, guaranteeing protection from high drug costs for those who need the protection Medicare has traditionally provided: the sickest and the poorest beneficiaries.

In addition to the “mystery” of what drugs will be covered, the “mystery” will be left up to the private insurance companies and not seniors.

H.R. 1 would end Medicare as we know it and may particularly harm rural areas. H.R. 1 would end Medicare as we know it and may particularly harm rural areas. Seniors who live where hospitals and doctors negotiate lucrative contracts with managed care plans would have to pay more; seniors with higher incomes would have to pay more; seniors in rural areas would have fewer choices of doctors and pharmacies; and seniors with low incomes but with assets such as a savings account might get nothing at all.

This means that there will be fewer choices—no those choices at all—for seniors in rural areas.

In one fell swoop, this bill takes the great success story that is Medicare: Universal health care for all beneficiaries and crushes it. Under the Republican bill, your benefits and your costs depend on your income, where you live and the whim of the insurance company or HMO that is running the program in your area.

Speaker, I have received many letters and calls from my constituents who are worried about this proposal. They know that this proposal will cost them more money, may not even be available to them if they live in rural areas and they will particularly harm rural areas. "We are not going to get the same benefit that Medicare has always worked. That is, it is a guaranteed benefit for all seniors, no matter where they live, how ill they are, or what kind of illness they have."

This bill proposes to turn the prescription drug benefit over to HMOs and the private insurance industry. The silent assumption in H.R. 1 is that drug prices will not be higher under this act. That drug prices will become higher is the central assumption of the Republican plan. The assumption is that the insurance industry would be able to charge what ever they wanted for the premium. In addition, it would be the insurance companies that get to decide who gets drugs and who does not.

This means for seniors is that there will not be a consistent, reliable program for all seniors is that there will not be a consistent, reliable program for all seniors across the country. Seniors in my district might pay higher premiums and get less coverage than their counterparts in other areas of the country. Or, they may get better coverage for lower premiums. We just don’t know because it will be left up to the private insurance companies and the HMOs.

This bill also raises out-of-pocket costs for those who need the protection that Medicare has traditionally provided: the sickest and the poorest beneficiaries. In addition to the “mystery” of what drugs will be covered, the “mystery” will be left up to the private insurance companies and not seniors.

Everyone knows that for private companies, the bottom line rules. Rural areas aren’t as profitable for insurance companies, so there is less incentive for them to offer benefits in those area. This means that there will be fewer choices—no those choices at all—for seniors in rural areas.

In one fell swoop, this bill takes the great success story that is Medicare: Universal health care for all beneficiaries and crushes it. Under the Republican bill, your benefits and your costs depend on your income, where you live and the whim of the insurance company or HMO that is running the program in your area.

Mr. Speaker, I urge my colleagues to do the same.
Dear Sir, I am writing my Senators and Representatives to plead our case regarding Medicare proposals that could endanger patient access to chemotherapy. I am a lung cancer survivor, age 72, and my husband, age 78, is now undergoing chemo, for liver cancer. Chemo drugs are required for my husband’s quality of life now and MRI’s have shown the tumor size diminished in size, so “it’s working!”

She goes on to say, “We in the cancer community want one thing: for all critical cancer services, including chemotherapy and patient care services to be covered fully and fairly by Medicare.”

Mrs. Monk makes a good point. Services must be covered fully and fairly by Medicare. It does seniors no good to have unequal coverage of medications! That is why I cannot support the Republican bill and I urge my colleagues to vote against this poison pill for Medicare!

Mr. PASTOR. Mr. Speaker, I rise today in opposition to the Medicare Prescription Drug and Modernization Act. This bill, long heralded by the Administration as a comprehensive overhaul of the Medicare system, will do nothing to alleviate the high cost on our seniors of the high cost of prescription drugs. It will only continue to aggravate the cause of health care inflation.

Despite claims to the contrary, the bill, which calls for private drug-only plans, would not make drugs affordable. It has no mechanism for keeping prices down, no negotiation for acceptable terms, no guarantee of defined and stable costs. Seniors would be at the mercy of private plans. They would lose their choice of doctors. They would be at risk of continuous coverage.

Private plans would only have to promise to stay in the program for one year. We’ve had these problems before with the Medicare Plus Choice program which failed to deliver its expanded benefits, leaving millions of seniors out on a limb.

Seniors have voiced their concerns. They fear the absence of provisions to limit drug prices and the lack of certainty about the future of the Medicare prescription drug benefit. Seniors in rural areas are worried because they have no access to private plans and would have no “fallback” to offer coverage. Seniors are particularly concerned with the “gap-in-coverage” that means no coverage at all for drug spending between $2,000 and $5,100.

Instead of passing this plan which would privatize Medicare, we should support a plan that would establish a real Medicare prescription drug benefit within the Medicare program. The plan should be available to everyone regardless of income or place of residence. It should be voluntary and comprehensive. And, most importantly, it should be affordable.

The Medicare Prescription Drug and Modernization Act fails none of these requirements. Therefore, Mr. Speaker, I vote “no” on H.R. 1. Ms. WOOLSEY. Mr. Speaker, this debate is a question of priorities, and it’s a question of values. Under the Republican plan, after seniors have incurred $2,000 in prescription drug benefits, they will still pay a premium, but they better not expect anything in return. And why is that? It’s because just last week, the Republican leadership decided that they would rather eliminate estate taxes for millionaires than help seniors afford prescription drugs. They insisted on spending a total of $820 billion to help 8,000 millionaires. For almost the same cost, we could give millions of seniors a real prescription drug benefit.

Millionaires or millions of seniors? The Republicans give new meaning to the phrase “better off dead.” If you’re rich and dead, Republicans don’t want you to lose your money. But if you’re alive and can’t afford the high cost of prescription drugs—well, good luck.

You might want to be dead. I dare my Republican colleagues to tell their mothers what they’re doing to Medicare.

My priority is giving every American senior a real prescription drug benefit, like the one in the Democratic alternative. Oppose the Republican bill, support the Democratic alternative.

Mr. OBERSTAR. Mr. Speaker, Medicare, the most successful social service program since Social Security, will be dramatically transformed and, in the long run, unravelled by this Republican bill we are debating tonight.

Their plan will convert Medicare from a defined benefit plan to a defined contribution voucher plan. In plain English, it means that seniors will lose the guaranteed coverage and the security of knowing which benefits are covered. Instead of having predictability about Medicare premiums and copayments, seniors will essentially receive a voucher for services they must purchase in an unregulated insurance plan. If this plan does not pay for the services they need, seniors will have to cover the difference—which would be a big figure—out of their own meager income.

As a result, this untested, speculative health care experiment would force seniors to abandon all seniors, especially rural seniors. The Republican bill replaces Medicare with an illusory promise that private health insurance companies will offer health insurance policies in rural America. Under current law, health insurance companies have found it unprofitable to offer policies in rural America; worse, the Republican plan does not guarantee that rural seniors will have access to the same benefits as seniors in metropolitan areas enjoy.

Not only does this bill undermine Medicare, it fails to provide an affordable prescription drug benefit. I don’t understand how the majority, on the one hand can justify trillion dollar tax cuts, and on the other hand, impose an arbitrary limit on Medicare prescription drug benefits. To comply with this artificial limitation, the Republican plan offers a complicated and untested prescription drug benefit, with an enormous gap in coverage.

The Republican plan is difficult to explain, but let me try: it begins with uncertain private health insurance premiums; then, seniors must pay $2,000 and $3,500, a deductible any senior can afford, and there is a large coverage gap, the “hole” in the doughnut, where seniors will be paying premiums but receiving no assistance at all. Seniors first have to spend $250 a year, then they will pay 20 percent co-insurance for up to $2,000 in drug costs. However, no assistance would be provided between $2,000 and $5,100 in drug spending, forcing seniors to pay $3,100 out-of-pocket in drug costs. This plan is as unfair as it is complicated and costly to older Americans living on fixed income.

In contrast, the Democratic plan is guaranteed, defined, dependable, and understandable. It sets a premium of $25 a month; a $100 per year deductible; a 20 percent co-insurance payment for beneficiaries, with Medicare paying 80 percent; and a limit of $2,000 in out-of-pocket costs per beneficiary per year.

Health care is essential in greater Minnesota. The hospitals in many small communities throughout northern and northeastern Minnesota are the major employer in town, and the health care they offer is critical for economic development and tourism. The Range/Dingell bill offers a substantial improvement in payments to the hospitals and doctors in rural Minnesota who provide those critical health care services.

I hope, Mr. Speaker, that the Democratic alternative includes provisions to improve reimbursement for rural providers. The increased funding for low-volume, “critical access” and “sole community” hospitals, rural home health and ambulance providers, and rural physicians adds up to very significant improvements for hospitals in my district, and will assure their continued viability for years to come.

To be specific, the Democratic bill eliminates the 35-mile rule presently in place for Critical Access Hospital services. That improvement would save the hospital in Ely, Minnesota, and would strengthen ambulance services at nine other Critical Access Hospitals in my district.

The Democratic plan would provide an additional billion for all rural ambulance providers by increasing payments for ambulance services. The increases we propose would ensure the financial solvency of St. Mary’s Life Flight, enabling it to continue assisting, for example, people who are injured while vacationing in the Boundary Waters Canoe Area Wilderness.

On the whole, rural health care providers’ plan are better served, better funded, and treated more fairly under the Democratic plan, which also has the advantage of preserving Medicare. For that reason, I will support the Range/Dingell bill.

Mr. BURR. Mr. Speaker, as vice chairman of the Energy and Commerce Committee and a member of the Health Subcommittee, I have worked on Medicare prescription drug legislation for more than four years. The House has passed Medicare prescription drug legislation twice and I voted for both bills.

Mr. Speaker, I will not vote for this bill.

The $400 billion allocated for the Medicare drug benefit is not being spent widely under this legislation. High-income Medicare beneficiaries like Warren Buffett are subsidized 73 percent by the Federal government for their drug-only insurance plans. Low-income seniors who are not dually eligible have no cost-sharing assistance for their drug spending between $2,000 and $3,500. The Secretary is commanded to negotiate with insurance companies who will game the system to receive a 99.99-percent subsidy when 73 percent would have been fine. Mr. Speaker, that’s not a negotiation—the insurance company will hold all of the cards. No money is being spent on a fallback plan. Seniors in rural areas of North Carolina will not have drug coverage if insurance companies refuse to offer a plan, even when the companies are bribed with an almost no-risk contract. This bill would benefit insurance companies, not extend a benefit to our Nation’s seniors.

Yet insurance companies do not want any part of this legislation. For four years insurance companies have been telling Congress...
that they do not want to insure Medicare beneficiaries' drug expenditures, but we keep throwing money at them in the hope that they will finally say yes. The premium subsidy used to be 67 percent, now it is 73 percent and Congress demands that it grow to 99.99 percent if need be. At the end of the day, who are we kidding? Of course it will be 99.99 percent.

Our problem is that the Congressional Budget Office has written this bill. The last time I checked, Mr. Speaker, it was not the job of the Congressional Budget Office to write highly technical and important health care legislation. But policymakers are so convinced that a purely insurance-based product will work that they are willing to follow CBO's instructions and tweak the product one thousand different ways—and cut provider payments at the same time—to fit it under some magical budget ceiling. If CBO is wrong in its estimate, and this drug benefit costs more than $400 billion, our entire health care system will be at risk. This is not wise health care policy.

Where do my colleagues think the extra money is going to come from? When CBO realizes that their estimated insurance penetration rate was off by 10 percent that money will come out of future physician, hospital, nursing home, and home health care reimbursement rates. If only 85 percent of seniors sign up for drug coverage and plans' subsidies skyrocket, that money will come out of Food and Drug Administration modernization efforts, National Institutes of Health research, and bioterrorism preparedness. Congress is working with a limited pot of money, but we are promising a defined benefit. Obviously, the experiences of the private sector have taught us nothing.

If Congress listened to the private sector, we would mirror the success of defined contribution plans and individual empowerment by offering choice. Seniors could choose between twenty different discount drug cards based on the cards' formularies, pharmacy networks, and drug discounts. The government would set up accounts and contribute money to those accounts based on the seniors' needs. In the same way, CBO has been quoted as saying that former employers could put money into the accounts and receive a tax deduction. And insurance companies would offer catastrophic coverage that is subsidized by the federal government for low-income seniors. Unfortunately, that plan is not on the floor today.

Mr. Speaker, I wanted to be able to come to the floor today and vote for a good Medicare prescription drug benefit because of the bills passed by the House in the last 3 years which this one has the greatest chance of actually becoming law. But not only does this bill have a drug benefit, it also contains a cut in the overall hospital market basket update, a new home health copayment, multiple reimportation provisions that will harm our Nation's drug supply, and a reduction in the overall reimbursement rate for physicians such as oncologists and rheumatologists who administer Part B drugs. It also constitutes a threat to the very future of our health care system.

I can only compare my feelings today to my experience in 1993 when I voted against the Balanced Budget Act. I was one of only 32 Republicans who opposed that bill. I came to Congress to balance the federal budget, but in the end I could not vote for the legislation because of the drastic and thoughtless cuts in Medicare reimbursements. Since 1997, Congress has done nothing substantive in Medicare except try to fix the damage done under the BBA. I cannot support this legislation that builds on and magnifies those 6-year-old mistakes.

I regret that I cannot and will not vote for this legislation.

Mr. UDALL of Colorado. Mr. Speaker, I want to support a Medicare prescription drug bill, but I can't support the one we are considering today. It would force seniors into HMOs, and will endanger drug benefits that many seniors get through their retirement plans. In fact, instead of drafting a Medicare drug benefit bill, the Republican Majority has used this opportunity to try to end Medicare as we know it.

I have long believed that Congress should act to help seniors with their prescription drug expenses. Nearly everyone agrees that Medicare should be updated with a drug benefit; it is the right and sensible thing to do. How we design that benefit is where the rub is. I had spent the week in D.C. drafting a bill similar to the one in the Senate because I think it’s a good start toward building a workable, financially sound prescription drug benefit. But the House bill is not the same as the Senate bill.

First, I think Congress should give seniors greater access to coverage. I do not believe it should provide an equal prescription drug benefit to all beneficiaries, regardless of whether they enroll in a private health plan or traditional fee-for-service Medicare. We shouldn’t force seniors into managed care, which I believe this bill works to promote instead of the traditional Medicare program up to competitive bidding against private insurers in 2010.

Second, the House bill does not include an important “fallback” provision that requires that traditional Medicare would step in as a backup if private insurers show no interest in selling drug plans in a particular area. Currently, private plans don’t exist in many parts of the country, including many smaller cities, rural and mountain areas in Colorado. I’ve heard from many seniors in my district who have been dropped from their HMOs and are now having trouble finding a doctor. In addition, 88 percent of all Medicare beneficiaries are enrolled in traditional Medicare. So, without this “fallback” safety net provision, seniors would have no coverage in regions where insurers say it’s unprofitable to provide it, especially rural areas.

Taken together, I think these provisions undermine the traditional Medicare program. By opening traditional Medicare to competitive bidding and with no fallback mechanism, I fear that our country will revert to the time before Medicare was established in 1965 when private insurers wouldn’t provide affordable coverage to seniors. That’s a step backward, not a step forward, in fixing Medicare.

I also have problems with the home health copayment provision in the bill, which I believe will discourage seniors from accessing home health care, which is more cost effective than accessing treatment an emergency room or a skilled nursing facility. And I am concerned that opening durable medical equipment to competitive bidding will give seniors less choice and put many small businesses out of business.

On top of everything, this 692-page bill was introduced at midnight last night. How can anyone know what’s in it, except the people who wrote it? Our seniors deserve greater respect.

Mr. Speaker, it is misguided at best that Medicare will pay for a senior’s care following a stroke but will not pay for the anti-hypertension drugs that prevent them. The time is ripe to pass a Medicare prescription drug benefit, but not this one. I regret I can’t support it. I hope that a bill can be worked out in conference that I can support. We need to put ideological and partisan politics aside and get it done this year.

Mr. CROWLEY. Mr. Speaker, I rise in support of the Democratic substitute because this bill meets the 4 basic tenets that any prescription drug plan under Medicare should absolutely provide for. First, it means lower drug prices. The House Democratic bill allows HHS to negotiate lower drug prices. The Republican bill, unfortunately, does not.

Second, this bill guarantees coverage under Medicare.

Because of this, a senior knows what his premium, cost-sharing level, and catastrophic coverage is. The Republican bill has no such guarantees.

Third, this bill provides coverage for all drugs prescribed by a doctor. Under the Republican bill, a payer could deny coverage for a drug if the payer decides to not include it in its pharmacy.

Fourth, this bill has no gaps in coverage. Under the Democratic plan, when a senior has spent $2,000 on drugs, the government picks up the remaining costs. The Republican plan has spent $2,000 under the Republican plan, they’re dropped. They get zero coverage until they’ve spent $4,900. The Republican bill does not simply have one big problem. It has several huge problems.

Only the Democratic substitute provides seniors in my district guaranteed, quality coverage. I urge an “aye” vote.

Mr. BUYER. Mr. Speaker, I rise in opposition to the bill. H.R. 1, the Medicare Prescription Drug and Modernization Act.

I fully support the effort to provide prescription drug coverage to Medicare beneficiaries. The successes in modern medicine that we see today can be partly attributed to the advanced and more effective pharmaceutical drug therapy. Illnesses and serious diseases that often required hospitalization 40 years ago, when Medicare was created, can now be treated with outpatient care and pharmaceuticals. This is a testament to the many and numerous companies that toil daily to find compounds to treat and manage disease. The pharmaceutical industry is a testament to the free market system of the United States that rewards hard work, initiative, and enterprise. As the great minds of the world push the bounds of modern science, new discoveries in pharmacology lead to the betterment of mankind.

While H.R. 1 has some positive features, including addressing medical doctor and dentist provider reimbursement concerns and regulations, and allowing Medicare to get a discount on an insurance product built and guaranteed by the government is not the approach to provide a drug benefit under Medicare. And, make no mistake, we MUST get it right.

First, the legislation before us has the government assuming 73 percent of the risk of offering the insurance, 43 percent of the initial...
benefit and 30 percent of reinsurance retroactively. This is the floor! We must all understand that the taxpayer’s exposure to risk can only increase. The bill permits the government to assume more risk, up to 99.9 percent if it is necessary to entice an insurance product into a region. This is an unknown factor. We nor cannot know what this provision will cost the taxpayers.

Today, Medicare already consumes nearly 12 percent of the federal budget. It is expected to be 30 percent or 35 percent of the federal budget by 2015, even if the Congress makes no changes to the Hatch-Waxman law. Initiating more litigation of patent rights is not conducive to encouraging innovation in pharmaceuticals. Unfortunately, this is exactly what this provision will do.

The vast majority of seniors have drug coverage today through either an existing government sponsored prescription drug plan or some form of private sector. However, 27 percent of seniors have nothing. These seniors pay the highest prices when they go to the pharmacy because they have no means to bargain for lower costs. These seniors also tend to be those between 100 percent and 175 percent of the federal poverty level. They should not displace existing coverage and should address the needs of those seniors who do not have coverage.

The government should encourage employers, families and others to help seniors with the purchase of expensive prescription drugs. It is time that we admit that no proposal that comes to the House floor that meets the budget requirements will fully address all the prescription drug requirements of seniors. Every plan will have a “so-called donut hole.” There should be a safety net without putting our heads in the sand and expecting it to simply “work out.”

We live by a system of checks and balances. We run into the limitations with everything that we do. How can we then create a process that is unknown? The government’s assistance to beneficiaries should be a defined contribution. This type of benefit would be manageable and known.

I am committed to providing a prescription drug benefit for seniors. Seniors should have access to medications that are available in the private sector to drive down costs and improve health services. Along with four of my colleagues on the Energy and Commerce Committee, we submitted legislation, that would address these issues and provide a prescription drug benefit under Medicare. I testified before the Rules Committee to request a vote on our bill. The request was denied. This benefit would have been delivered through a prescription drug discount, or value, card that would be available to all seniors with a voluntary basis for an annual $30 fee. This is an approach that has been recommended by the President. Any entity qualified by the Centers for Medicare and Medicaid Services could offer a drug card to seniors. Card issuers would negotiate with pharmaceutical manufacturers for discounts on drug utilizing the same techniques that are found in the marketplace today. These discounts would range from 15 percent to 35 percent of current retail prices. The competition among these card issuers would result in attractive offerings to beneficiaries.

Recognizing that some beneficiaries need financial assistance to pay for prescription drugs, this legislation would tie the drug value card to an account to which the federal government would provide assistance related to the income of the beneficiary. Others could add contributions on a tax preferred basis up to $5,000 for a beneficiary and family; and $5,000 for an employer. Non-profit organizations, like local churches, and State pharmaceutical assistance programs could add contributions to the accounts. Contributions on the accounts would roll over from year to year.

Protection from catastrophic drug expenses would also be offered at $10,000 through the private sector, with federal subsidies on the premium for those with low incomes.

In my opinion, this delivery mechanism for a prescription drug benefit works best for the beneficiary, and best for the taxpayers. Beneficiaries would have access to negotiated discounts and some form of assistance to buy drugs. The taxpayers would have a defined contribution that could be planned from year to year in the federal budget.

My colleagues, this has been a long road for us all. But, it is nothing compared to what Congress gets wrong. Please be mindful of our obligations to our nation, not just to seniors.

It is my opinion that Congress needs to grasp this opportunity to provide a prescription drug benefit with a full appreciation of the duty and responsibility this nation has to our seniors, taxpayers, and future generations. To do anything less, we break the trust of all Americans.

Because the margin for error is so thin, my hope is that the majority is right. However, my instinct and instinct today is that this bill will not fulfill the desired result. I must vote against final passage of this measure.

Mr. PAUL. Mr. Speaker, while there is little debate about the need to update and modernize the Medicare system to allow seniors to use Medicare funds for prescription drugs, there is much debate about the proper means to achieve this end. However, much of that debate is phony, since neither H.R. 1 nor the alternative allows seniors the ability to control their own health care. Both plans give a large bureaucracy the power to determine which prescription drugs seniors receive. Under both plans, federal spending and control over health care will rise dramatically. The only difference is that the alternative puts seniors under the total control of the federal bureaucracy, while H.R. 1 shares this power with “private” health maintenance organizations and insurance companies. No wonder supporters of nationalized health care are celebrating the greatest expansion of federal control over health care since the Great Society.

I am pleased that the drafters of H.R. 1 incorporate the regulatory relief legislation, which I have supported in the past, into the bill. This will help relieve some of the tremendous regulatory burden imposed on health care providers by the Federal Government. I am also pleased that H.R. 1 contains several good provisions addressing the congressionally-created crisis in rural health and attempts to ensure that physicians are fairly reimbursed by the Medicare system.

However, Mr. Speaker, at the heart of this legislation is a fatally flawed plan that will fail to give seniors a fair choice and threaten the pharmaceuticals of their choice. H.R. 1 provides seniors a choice between staying in traditionally Medicare or joining an HMO or a Preferred Provider Organization (PPO). No matter which option the senior selects, choices about which pharmaceuticals are available to seniors will be made by a public or private sector bureaucrat. Furthermore, the bureaucrats will have poor to determine the aggregate prices charged to the plans. Being forced to choose between types of bureaucrats is not choice.

Thus, in order to get any help with their prescription drug costs, seniors have to relinquish their ability to choose the type of prescriptions that meet their own individual needs! The inevitable result of this process will be rationing,
as Medicare and/or HMO bureaucrats attempt to control costs by reducing the reimbursements paid to pharmacists to below-market levels (thus causing pharmacists to refuse to participate in Medicare), and restricting the type of pharmacies seniors may use in the name of savings. But experience shows that seniors may even go so far as to forbid seniors from using their own money to purchase Medicare-covered pharmaceuticals. I remind my colleagues that today the federal government prohibits seniors from using their own money to obtain medications that differ from those “approved” of by the Medicare bureaucracy!

This bill is even more pernicious when one realizes that this plan provides a perverse incentive for private plans to dump seniors into the government plans. In what is likely to be a futile effort to prevent this from happening, H.R. 1 extends federal subsidies to private insurers to bribe them to keep providing private drug coverage to senior citizens. However, the Joint Economic Committee has estimated that nearly 40 percent of private plans that currently provide prescription drug coverage to seniors will stop providing such coverage if this plan is enacted. This number is certain to skyrocket once the pharmaceutical companies begin to perceive the financial consequences caused by Medicare price controls to private plans.

Furthermore, these private plans will be subject to government regulations. Thus, even seniors who are able to maintain their private coverage will fall under federal control. Thus, H.R. 1 will reduce the access of many seniors to the prescription drugs of their choice!

Setting up a system where by many of those currently receiving private coverage are hired into the government program exacerbates the problems with this bill; it hastens the bankruptcy of the Medicare program and the federal government. According to Medicare Trustee, and professor of economics at Texas A&M University, Tom Saving, the costs of this bill could eventually amount to nearly $3.8 trillion! Of course, estimates such as this often widely underestimate the costs of government programs. For example, in 1965, the government estimate that the Medicare Part B hospitalization program would cost $9 billion in 1990, but Medicare Part B costs $66 billion in 1990!

This new spending comes on top of recent increases in spending for “homeland security,” foreign aid, federal education programs, and new welfare initiatives, such as those transforming churches into agents of the welfare state. In addition we have launched a seemingly endless program of global reconstruction to spread “democratic capitalism.” The need to limit spending is never seriously discussed: it is simply assumed that Congress can spend whatever it wants, relying on the Federal Reserve to bail us out of trouble. This is a prescription for disaster.

At the least, we should be debating whether to spend on warfare or welfare and choosing between care and welfare, the poor instead of simply increasing spending on every program. While I would much rather spend federal monies on prescription drugs then another unconstitutional war, increasing spending on any program without corresponding spending reductions endangers our nation’s economic future.

Congress further exacerbates the fiscal problems created by this bill by failing to take any steps to reform the government policies responsible for the skyrocketing costs of prescription drugs. Congress should help all Americans by reforming federal patent laws and FDA policies, which provide certain large pharmaceutical companies a government-granted monopoly over pharmaceutical products. Unfortunately Congress can do to reduce pharmaceutical policies is liberalize the regulations surrounding the reimportation of FDA-Approved pharmaceuticals.

As a representative of an area near the Texas-Mexico border, I often hear from angry constituents who cannot purchase inexpensive quality imported pharmaceuticals in their local drug store. Some of these constituents regularly travel to Mexico on their own to purchase pharmaceuticals. It is an outrage that my constituents are being denied the opportunity to benefit from a true free market in pharmaceuticals by their own government.

Supporters of H.R. 1 claim that this bill does liberalize the rules governing the importation of prescription drugs. However, H.R. 1’s importation provision allows the Secretary of Health and Human Services to arbitrarily restrict the ability of American consumers to import prescription drugs—and HHS Secretary Thompson has already gone on record as determined to do all he can to block a free trade in pharmaceuticals! Importation language in H.R. 1 is a smokescreen designed to fool the gullible into thinking Congress is acting to create a free market in pharmaceuticals. The alternative suffers from the same flaws, and will have the same (if not worse) negative consequences with H.R. 1. There are only two differences between the two: First, under the alternative, seniors will not be able to choose to have a federally subsidized HMO bureaucrat deny them their choice of prescription drugs; instead, seniors will have to accept the control of bureaucrats at the Center for Medicare and Medicaid Services (CMS). Second, the alternative is even more fiscally irresponsible than H.R. 1.

Mr. Speaker, our seniors deserve better than a “choice” between whether a private or a public sector controls their health care. Meaningful prescription drug legislation should be based on the principles of maximum choice and flexibility for senior citizens. For example, my H.R. 1617 gives seniors the freedom to freely import FDA-Approved pharmaceuticals. It is an outrage that my constituents who cannot purchase inexpensive quality imported pharmaceuticals in their local drug store. Some of these constituents regularly travel to Mexico on their own to purchase pharmaceuticals.

In conclusion, Mr. Speaker, both H.R. 1 and the alternative force seniors to cede control over which prescription medicines they may receive. The only difference between them is whether H.R. 1 gives seniors the freedom to freely import FDA-Approved pharmaceuticals and HMO bureaucrats control over seniors’ prescription drugs, whereas the alternative gives government bureaucrats the power to tell seniors which prescription drug they can (and can’t) have. Congress can, and must, do better for our Nation’s seniors, by rejecting this command-and-control approach. Instead, Congress should give seniors the ability to use Medicare funds to pay for the prescription drugs of their choice by passing my legislation that gives all seniors access to Medicare Medicaid Accounts.

Mr. THORNBERY. Mr. Speaker, health care is an important but complex issue for Congress and for America’s seniors. Two facts, however, seem clear: one is that Medicare is currently headed toward financial collapse. The last report of the Medicare trustees shows that in nine years the income of the Medicare trust fund will not be enough to cover its expenses. After that, the problem gets much worse with the retirement of the baby boom generation. A second clear fact is that Medicare was enacted in 1965 and has been largely unchanged since then. It does not reflect modern...
medical practices, including our reliance upon prescription drugs. If we were designing a new federal health care program for seniors today—rather than in 1965 when Medicare was created—we would unquestionably include some form of prescription drug coverage.

Our objective then should be to update and strengthen Medicare so that it does a better job of providing health care for seniors and at the same time put Medicare on a sound financial footing so that it can be sustained through the baby boom generation retirement. This bill takes some steps in that direction. It contains some reforms that improve Medicare and give beneficiaries more control over their health care. It also adds prescription drug coverage, and there are too many seniors in my district who are not able to afford the prescription medicines they need, forcing them either to do without and become sick or to sacrifice other necessities of life.

I am gravely concerned, however, that the reforms take too long to implement and that the new drug benefit will cost far more than expected. Without changes, this bill may add a major new benefit to Medicare but, at the same time, hasten the day of its financial collapse.

At the same time if we do nothing, we are guaranteeing that Medicare will not survive for long. None of the alternative proposals are far more expensive and are fiscally irresponsible.

I have other concerns with this bill, such as the reductions in payments for cancer treatments. Today, however, I will vote to send the House bill to conference with the Senate. I strongly urge that improvements be made to ensure Medicare solvency and to improve the quality of health care for America’s seniors. We can do better. If improvements are not made, I will not be able to support the final conference report.

Mr. KIND. Mr. Speaker, providing affordable Medicare prescription drug coverage for our nation’s seniors is one of the most pressing issues facing our country today. Even though the elderly use the most prescriptions, more than 75 percent of seniors on Medicare lack reliable health insurance. It is time for us to modernize Medicare to reflect our current health care delivery system. The use of prescription medications is as important today as the use of hospital beds was in 1965 when Medicare was created.

I have heard from a number of seniors in western Wisconsin regarding the problems they have paying for prescription drugs. One woman from Deer Park, Wisconsin, a small town in my district, wrote to me and said:

My medication is $135.00 per month. Fortunately, I am not on any medication. If we both were not working part-time, I guess that we would have to make a choice between food and medication—does one eat to survive or take the medication for a “long and happy life.”

What is to happen to this couple if the husband falls ill and has high drug costs too?

The cost of prescription medicines should not place financial strains on seniors that would force them to choose between buying drugs and buying food. We need to make prescription medicines affordable and accessible to all of our seniors.

I came to Congress to work toward a real solution to this problem. Unfortunately, today’s debate is a sham. We will not have the opportunity to discuss this issue in a fair and open process. There were several alternatives presented at the Rules Committee late last night and they should be debated on the floor today. The majority, however, chose to dedicate only one day to this debate and allowed only one alternative and no amendments to be made. Order seniors deserve better. They deserve an open process, but the Republican leadership has failed to deliver this.

The Leadership has also failed seniors with their prescription drug proposal. The Republican plan that relies on health insurance companies to offer drug only policies which they have said they won’t offer. Further, there is no fall back option. So, if insurance companies won’t offer these policies, how will seniors actually obtain prescription drug coverage under the leadership plan?

Providing a drug benefit through private plans could be problematic, specifically for folks living in rural and small communities. There are no requirements as to what has to be covered. There are no limits as to how they can divide the coverage among seniors area to area depending on the plan. Because is there is no guaranteed benefit, Wisconsin may end up on the short end of the stick like we have in the past under Medicare.

The biggest problem with the leadership bill is that the fact that experience with Medicare in 2010. This is a radical provision that will be the demise of the traditional Medicare program on which our seniors have depended for nearly 40 years. In 2010, seniors will be given a lump sum to purchase health insurance, including traditional Medicare. There is concern that the healthy seniors will leave traditional Medicare and the premiums will increase dramatically, up to 47 percent. In addition, under the leadership bill, each local area will have a different premium for fee-for-service Medicare. For example, seniors in Wisconsin might have to pay more to enroll in fee-for-service Medicare than seniors in Florida. This is a drastic departure from Medicare’s fundamental principle that seniors across the country pay the same premium for the fee-for-service benefit.

It is time to provide a real solution to the problem of prescription drug coverage for our seniors. The Republican plan fails woefully short. All of the Democratic alternatives offered at the Rules Committee would be better than the leadership bill. One proposal, the Medicare Rx NOW Act, is a simple straightforward plan that provides assistance to the seniors most in need, those with low incomes and seniors with high drug costs. This proposal builds on the Medicare program seniors know and provides them with a guaranteed benefit for no additional cost. Another proposal put forward by the Blue Dogs is based on the bipartisan Senate bill. Unlike the House bill, this proposal includes a fall back provision to ensure that all seniors would have access to a prescription drug plan. In addition, this bill does not include the privatization components of the leadership plan.

In addition, both of these alternatives provide substantial improvements to Medicare payments for rural providers. Both pieces of legislation include equalizing the disproportionate share hospital payments for rural hospitals, an increase in the bed limit for critical access hospitals, and a geographic adjustment for rural physicians. None of these provisions are included in the leadership’s bill.

It is unfortunate that the Republican leadership has squandered an excellent opportunity to try and solve the problem of prescription drug coverage in a bipartisan fashion. Instead they have steamrollered ahead and present our nation’s seniors with an unworkable solution to a grave problem. I urge my colleagues to reject this flawed proposal. Mr. RAMSTAD. Mr. Speaker, I rise in strong support of the Medicare Prescription Drug and Modernization Act.

Today is an historic day. Congress is finally delivering on our promise to create a meaningful and long overdue prescription drug benefit for Medicare seniors and people with disabilities.

This bill means seniors will no longer have to choose between purchasing life-saving drugs or the basic necessities of food and housing.

In addition to this important new prescription drug benefit, the bill modernizes and improves Medicare to give seniors better choices and greater access to state-of-the-art health care.

I am grateful for the many important provisions in this package from my Medicare Innovation Responsiveness Act (H.R. 941), which will increase seniors’ access to lifesaving medical technology.

As founder and co-chair of the Medical Technology Caucus, I have seen first-hand the incredible advances that medical technologies and prescription drugs have made to treat and cure debilitating conditions. The current Medicare system is crying out for reform with its failure to incorporate these critical improvements.

Currently, seniors and people with disabilities face unconscionable delays of up to five years before Medicare provides access to technology that can literally be a matter of life or death.

The bill before us incorporates many of the reforms I have proposed in Medicare’s coverage, coding and payment process that will speed access to lifesaving technology.

Thanks to this legislation, we are finally tearing down barriers that discourage innovation and deny America’s seniors the medical technologies that they desperately need. Seniors have waited too long for access to the same treatment options as other Americans.

In addition to the excellent work and leadership of Chairman THOMAS and Chairman JENKINS, I want to thank my bill co-sponsors—John McManus and Deb Williams—who have worked so tirelessly on these provisions.

I am also pleased the bill includes H.R. 841, legislation I introduced with Mr. CARDIN to break down regulatory barriers facing specialized Medicare+Choice plans that serve the frail elderly.

Mr. Speaker, this package of reforms will improve the lives of our seniors and generations to come who count on Medicare. I urge my colleagues to support this landmark legislation and deliver on our promise to modernize and strengthen Medicare.

Mr. BACA. Mr. Speaker, I rise in opposition to H.R. 1, the Medicare Prescription Drug & Modernization Act of 2003.

This Republican plan is bad for seniors! It’s bad for Hispanics! And it’s simply bad for the American people!

For millions of Americans, this plan will replace traditional Medicare with vouchers that will force seniors to pay out of pocket for their drugs.

It forces seniors into risky HMO plans and new private fee-for-service plans that will not cover all of seniors’ costs!
A plan that offers coverage to all seniors—
even Hispanics! It’s time to take seniors off the bus to Tijuana!
Mr. MICAUD. Mr. Speaker, tonight the House of Representatives, considered a plan that would supposedly create a Medicare prescription drug benefit. While some touted the plan as an innovative approach, the fact is that when you look past the smoke and mirrors, it turns out to be a very bad deal for Maine’s seniors. In fact, the House plan could make the current situation for seniors a lot worse: it will do nothing to control rising prescription costs, it will jeopardize the traditional Medicare fee-for-service plan that seniors enjoy right now, it has a large gap in coverage that will force them to spend hundreds of dollars out of their pockets, and it may cause employers to drop their health coverage.
We all know that drug prices are spiraling out of control. Maine seniors are forced to take bus trips to Canada to buy affordable prescription drugs. Our seniors have to go all the way to Mexico to get the life-saving medicine they need.
This is not safe and it is not fair.
I am angered when I think about all of the people that the Republicans are leaving behind in their plan with nothing to spare.
Why are we letting this happen to our abuelos? Our parents and grandparents? How can we be so heartless?
When I think about this plan, I think about all of the seniors who can’t afford life saving prescription drugs.
I think about the senior who has glaucoma and prostate cancer and makes only $8,000 a year.
Like 750,000 other Hispanics, he won’t get help paying for his prescription drugs, because he is lucky enough to have assets and own a car.
According to Republicans, that is wealthy!
They will give tax breaks to millionaires, but under their plan, a man who makes $8,000 a year, and is lucky enough to have a car, is too wealthy to get medicines that will ease his pain and save his life!
This is an outrage!
Under the Republican plan he would have to sell his car and pass an assets test to be poor enough to receive aide for low-income seniors.
When I think about this plan, I think about the senior who might make $10,000 a year.
That senior will pay one-fifth of his or her income to cover the Republican coverage gap.
One-fifth! This won’t get him off the bus to Tijuana!
Like 63 percent of Americans, seniors in my district want and need the security of Medicare.
Under the Republican plan they may start in Medicaid.
But after a couple of years, Medicare will only be a voucher program and where will Medicare.
In an HMO plan and still in a pharmacy in Tijuana buying medicine.
My constituents deserve better than the Republican plan.
They deserve more!
They deserve the Democratic plan that we have been fighting for for years!
A plan that cares about the health and safety of America’s seniors!
A plan that actually works for America’s seniors!
For all these reasons, groups from AARP to the National Committee to Preserve Social Security and Medicare have sharply criticized this plan. I supported a number of alternative bills that would address the problems with this plan and vastly improve the benefit available to seniors. Unfortunately, the leadership of the House was not willing to push any bill through as quickly as possible with providing a quality benefit for seniors, and they weren’t willing to fix the serious flaws in the bill that could hurt seniors. In fact, the House leadership refused to allow even one real amendment to the bill.
I want to pass a real prescription drug benefit—but I would not vote for a plan that hurts Maine’s seniors. I am disappointed with the legislation that was passed by the House, however the fight for a real Medicare benefit is not over. It is my hope that this legislation will be improved in the upcoming conference with the Senate. I will continue to fight to make sure that all Maine seniors receive an affordable and real Medicare prescription benefit.
Mr. LANGEVIN. Mr. Speaker, I rise in opposition to H.R. 1, the Medicare Prescription Drug & Modernization Act. Like many of my colleagues, I held sincere hope that the 108th Congress would overcome the inaction that has plagued this issue, at the expense of America’s senior citizens, for many years. I am extremely disappointed that the bill before the House this week not only fails to offer a structurally sound prescription drug benefit for Medicare beneficiaries, but also contains provisions that threaten the stability of the program that has provided health benefits for millions of elderly people and younger adults with disabilities for the past 38 years.
In particular, I want to call attention to the fact that this bill does nothing to address the rapidly rising costs of prescription drugs. It not only fails to address this crisis, it contains a “noninterference” clause prohibiting the agents of the Department of Health & Human Services from using the bulk purchasing power of Medicare beneficiaries to negotiate for lower prices for senior citizens. Without taking measures to curb the escalating prices of prescriptions, it’s simply not possible for seniors to stay alive, the benefit is rendered meaningless.
Seniors will pay more out of pocket in 2007 with the prescription drug benefit than they are paying in 2003 without it.
I urge my colleagues to pay careful attention to the details of the Medicare Prescription Drug & Modernization Act and to think critically about the effect—or lack thereof—it will have on the seniors in their districts.
Mr. ISRAEL. Mr. Speaker, I am proud to be a Democratic Member of this body. I have always been proud to be a Democrat. And always will be.
But I came to Congress 2½ years ago with a promise to my constituents that I would work hard to break through partisan gridlock. I promised that when I agreed with the Republicans I would vote with them; and when I disagreed I would vote against them. But that I would always work to develop consensus and move our country forward.
That is what brings me here today, Mr. Speaker.
A plan that cares about the health care crisis for seniors on Long Island. We used to have 12 Medicare HMOs in my communities. Now we have two
left. Eighty-five thousand seniors have been tossed out of their Medicare HMOs. One out of five is skipping their medication because they can’t afford them.

And in those 2½ years, I have listened to Republicans blame Democrats for this crisis; Democrats blame Republicans; the House blame the Senate; the Senate blame the House; Congress blame the White House; the White House blame Congress; and everyone blame the insurance companies.

There is plenty of blame to go around. But all the blame in the world isn’t going to help a single senior get their prescription drugs at a more affordable price.

It’s time to stop blaming. It’s time to stop finger pointing. It’s time for conservatives to stop railing against a $400 billion prescription drug plan because it’s too liberal. It’s time for liberals to stop railing against a $400 billion prescription drug plan because it’s too conservative. It’s time for everyone to stop rejecting the imperfect because we can’t get the perfect. It’s time to move this process forward.

Mr. Speaker, I believe the Democrats are right. We have a safety net, a $400 billion plan to provide America’s seniors with a truly comprehensive, voluntary prescription drug plan.

Is an $800 billion prescription drugs program better than a $400 billion program that’s before us today? Of course. $400 billion is only half as much as $800 billion. It is $400 billion better than nothing. And nothing is exactly what we will leave our seniors if we reject this proposal today.

To reject the largest expansion of Medicare in its 38-year history because it’s $400 billion instead of $800 billion just doesn’t make sense to me.

Mr. Speaker, only a short time ago, President Bush argued for a $190 billion prescription drug plan. My side of the aisle proposed an $800 billion plan. Some say we have ended up at a $400 billion plan.

I disagree. I think we are beginning with a $400 billion plan. It is the largest expansion of Medicare in its 38-year history. It is, in my view, a down payment. An investment.

Is this plan flawed? I believe it is. I believe the Secretary of Health and Human Services endorsed by Ted Kennedy, is much better. But we can’t get near that plan unless we go to a House-Senate conference. And we can’t go to a House-Senate conference unless we pass this bill today.

Yesterday at the White House, I listened carefully to President Bush. He said clearly we must move this process forward and pledged to work on a bipartisan basis to develop a final bill that represents consensus.

But there’s no hope for consensus, no hope for a penny of prescription drug spending, if we stall the clock on the process today by killing this bill today.

Mr. Speaker, of particular importance to me and the constituents I represent is that this bill contains the Greenwood-Israeli-Fossella amendment, which ends the economic discrimination in federal reimbursement formulas to suburban Medicare HMOs that have forced 85,000 of my constituents out of their prescription drug plans.

Those seniors are watching us today. They are tired of blame, tired of gridlock, tired of excuses. They don’t care whether it’s a Democratic or Republican solution, as long as it’s a good solution.

This is not a perfect solution. But it is a good start. It is the largest expansion of Medicare in its 38-year history. It ends the price discrimination on Long Island and other suburbs around the nation.

Mr. Speaker, let me close by repeating this: $400 billion is only half as good as $800 billion. . . . but it is $400 billion better than nothing. And nothing is exactly what we will leave our seniors if we reject this proposal today. In the spirit of advancing the process, I will support this bill. I reserve the right, however, to vote against a bill that emerges from Congress that does not address the significant flaws in the legislation before us tonight.

But, Mr. Speaker, this Republican Medicare bill falls well short of what our country’s retirees deserve. And I believe, that if this Congress and this President had not squandered the budget surplus we could afford to give our seniors a benefit they deserve.

It is well past time to assist our seniors with prescription drug costs. The Democratic substitute provides a reliable and affordable benefit to America’s seniors. This voluntary prescription drug coverage costs only $25 a month with a $100 deductible and provides a $2500 stop-loss protection with no gaps in coverage. There are also special provisions to help the poorest seniors with either full payment or assistance on a sliding fee scale.

The Democratic substitute I support also allows the Secretary of Health and Human Services to negotiate the price of the 40 million Medicare beneficiaries to negotiate lower drug prices. And as the ranking member on the Veterans’ Affairs Committee, I was proud to help craft a similar plan which has helped our nation’s veterans lower their out of pocket drug costs.

As a member representing a rural district, I also want to highlight the rural health care provisions included in the Democratic substitute. These provisions are essential to create equity in the reimbursement system between urban and rural hospital. They allow fair payments to hospitals that have a disproportionate share of low-income patients, increases payments to rural home health providers without requiring a co-pay, and adjusts low-volume payments for rural hospitals. It also takes into account the physiognomies of rural areas by finally correcting the huge disparity between urban rural hospitals, that drives providers from our small towns.

All of these reasons make the Democratic alternative to H.R. 1 the right answer to the spiraling costs for prescription drugs for seniors. Medicare works for America’s seniors but, I oppose the GOP’s efforts to privatize this system and provide a second-rate prescription drug benefit. I proudly support the Democratic substitute and I urge my colleagues to vote down H.R. 1 and vote Yes on the substitute.

Mr. CUMMINGS. Mr. Speaker, I rise today to speak against the inadequate Medicare prescription drug bill being considered today, H.R. 2473 and in support of the Rangel/Dingell Substitute.

With over 40 million elderly and disabled persons covered under the 38-year-old Medicare entitlement, Congress’ chief objective should be to ensure that these Americans have access to quality health care coverage. However, today we consider legislation that will do harm not because it is the first step in privatizing the Medicare program and as former Speaker Gingrich predicted, causing it to “wither on the vine.” Passage of this legislation will cause many of our seniors to wither right along with the Medicare program—which will no longer be seen as the social compact with our seniors that this nation embraces.

Medicare is the nation’s second largest social insurance program. As an entitlement program, it is imperative to realize that with the implementation of H.R. 2473, fee-for-service Medicare payments would naturally increase. This will result in many seniors facing the horrible prospect of being unable to afford the increased payments. I think many of my colleagues would agree that this is a very troubling proposition and a totally unnecessary result.

Additionally, with the reestablishment of the Voluntary Prescription Drug Benefit Program, seniors again would lose because of the lack of negotiated prices for the prescription drugs. Also, although federal subsidies would be provided to encourage participation, the bill would increase the annual out-of-pocket threshold for many beneficiaries. Once again a pseudo-solution creating a prescription drug benefit while increasing the cost for persons who need the benefit but will not be able to afford its costs.

Furthermore, the use of health maintenance organizations (HMOs) and other private organizations to obtain prescription drugs would deter many seniors from getting the benefit. As Rep. Charles B. Rangel, Ranking Demo- crat on the Committee on Ways and Means stated, “to get prescription drug coverage, seniors would have to go to an HMO by an- other name. Then, all the choices would be- long to the private insurance provider—which drugs are covered, which pharmacies you can choose, who your doctor is, etc.” Mr. Speaker, this bill is an empty pillbox—it is a paltry solution to the problem of providing adequate prescription drug coverage to our seniors; rather, it is creating an inadequate system—based on a provider concept that does not currently exist and will not likely work in practice.

A better alternative to H.R. 2473 is The Medicare RX Drug Benefit an Discount Act (H.R. 1199) offered by my friend CHARLIE RAN- GEL of New York. This prescription drug plan would guarantee that every Medicare bene- ficiary, no matter where they live, could have a benefit with a $25 deductible, $2000 annual deductible, 20 percent co-insurance and $2000 out-of-pocket limit. The bill would also:

1. Lower prescription drug cost for all Americans, regardless of whether they are covered by Medicare.

2. Give all Medicare beneficiaries the option of a reasonably priced guaranteed prescription benefit under Medicare;

3. Ensure that senior citizens and people with disabilities receive coverage for the drug that their doctor prescribes; and

4. Provide additional assistance for low-income beneficiaries such that many seniors would pay nothing for their prescription drugs.

Unlike the proposal put forth by the Bush Administration and endorsed and worsened by the House GOP Leadership, H.R. 1199 would not require seniors to join an HMO or similar private plan in order to get a prescription drug benefit. In fact, Medicare beneficiaries would be guaranteed a prescription drug benefit rather than offered a marginal, voluntary plan under H.R. 2473. This plan would ensure that we keep our social compact with our seniors. The Republican plan fails to do that.
Since its inception 1965, Medicare has provided important protection for millions of aged and disabled persons. H.R. 2473 would be a detriment to improving and securing this system. I tend my voice in opposition and urge my colleagues to vote against H.R. 4273 and to support H.R. 1.

Ms. WATERS. Mr. Speaker, I rise to oppose this Medicare privatization plan, which is masquerading as a prescription drug bill.

This bill would force seniors who want prescription drug coverage to get it from private insurance. It provides no guarantee that insurance plans will be available, and when they are, premiums and benefits will vary widely. The bill also provides no coverage when a senior’s prescription drug costs are between $2,000 and $4,900 per year. This huge coverage gap affects 47 percent of Medicare beneficiaries.

This bill is also a give-away to pharmaceutical companies, as it prohibits the Secretary of Health and Human Services from negotiating lower drug prices. The primary beneficiaries of this bill are not the beneficiaries of Medicare but the wealthy special interests in the pharmaceutical industry and the insurance industry that give campaign contributions to Republicans.

However, the most outrageous aspect of this bill is what it does to traditional Medicare. The bill cuts seniors’ cost for visits to the doctor’s office by raising the Medicare Part B deductible and indexing it for inflation. This could cost American seniors an estimated $8 billion. While this may seem like a tiny fraction of the Republicans’ $350 billion tax-cut-for-the-rich, it is a huge expense for senior citizens, many of whom live on limited incomes.

This bill also divides Medicare into 10 or more regional plans in 2006 and then converts the entire Medicare program into a voucher program depending upon private insurance companies in 2010. If the Republicans really want to privatize Medicare, they should be honest with the American people and call this bill what it is, the Medicare Privatization Act.

The Democrats alternative prescription drug plan on the other hand provides prescription drug coverage to all Medicare beneficiaries for a nominal fee. It guarantees and affordable premiums and benefits for all American seniors and no gaps in coverage.

It is time for Congress to make prescription drugs available to all seniors who need them.

I urge my colleagues to oppose the Republican Medicare Privatization Act and support the Democratic alternative.

Mr. ISTOOK. Mr. Speaker, this bill will hasten the day when Medicare will go bankrupt, and it also threatens to unravel our children’s future.

Medicare is already on shaky financial legs, and this will add enormous extra expenses that will make it worse. Do we expect our children to pay a lifetime of higher taxes, and still find there’s nothing left for them when they retire? That is what we face.

I would like to add prescription drug benefits, but convincing them to promise something we cannot pay for.

I want to preserve what’s good about Medicare, not destroy it by making extravagant promises for political gain.

The enormous extra spending under this bill will be far more than projected. Because today’s Medicare is a huge price control system, many doctors already refuse to see Medicare patients. In just a few years this will make it worse, including price controls that will destroy the incentives for comparators to create new medicines.

What should we be doing? Since 76 percent of seniors already have drug coverage, we could focus on helping those who don’t. We could provide the coverage for those 76 percent, and put them in a confusing new medical experiment.

We should be stabilizing Medicare, so it can keep the promises already made, not making new promises that we don’t have the money to keep.

We should address the reasons why drug prices and healthcare costs are so high. By banning re-imported drugs, we’re forcing Americans to subsidize far-lower drug prices in other countries. We should change our policies so Americans only pay the lower world price, not a higher price.

We should end the 130,000 pages of federal regulations that have driven the costs of medicine and healthcare through the roof. On average, for every hour they spend with a patient, doctors and nurses spend another half-hour to a full hour doing government paperwork.

We should stress personal responsibility in healthcare, just as we did in welfare reform, so government resources are focused on those who cannot care for themselves, not on those who can.

Bit-by-bit, Congress is undoing the principles of welfare reform, and undercutting basic American principles in the process. Both political parties are making extravagant promises today, trying to outbid each other to win votes. Very soon they will be bidding with taxpayers’ own money, and our children’s hopes will be crushed by the bills they inherit.

Mr. PORTMAN. Mr. Speaker, I rise to speak in suppurr of provisions in H.R. 1. The Medicare Prescription Drug and Modernization Act, that are designed to address the special pharmacy needs of beneficiaries residing in nursing homes.

Nursing home residents are not in a position to fill prescriptions like everyone else. They cannot simply walk into a pharmacy and have their prescription filled. Many nursing home residents, because of their physical or mental condition, are not able to take their prescription drugs on their own, especially if they have to take multiple medications throughout the day.

Their unique circumstances require specialized pharmacy care that retail and mail order pharmacies do not provide. Long-term care pharmacies meet these special needs.

They contract with nursing homes to provide specialized packaging, 24-hour delivery, infusion therapy services, geriatric-specific formulations, clinical consultation and other services that are critical to a nursing home.

Importantly, long-term pharmacies play a critical role in preventing medication errors that add to the cost of care and suffering of Medicare patients. In fact, one study estimates $3.6 billion in medication errors have been avoided as a result of long-term pharmacy care. I believe it makes sense to preserve specialty pharmacies’ ability to perform these vital services for nursing home residents, and I want to point out how H.R. 1 does this.

First, the bill requires the Secretary of Health and Human Services to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Prior to implementation of the prescription drug benefit, the Secretary will submit its findings to Congress on how long-term pharmacy services will be available to nursing home residents, including appropriate reimbursement levels for the specialty pharmacies that currently serve these nursing home residents.

The Secretary’s report is to include a detailed description of its plans and the timelines for provision of this legislation in a manner consistent with state and federal laws designed to protect the safety and quality of care of nursing facility patients.

Second, H.R. 1 directs plan sponsors to implement medication therapy management programs as a tool to reduce medication errors and improve patient outcomes. Long-term care pharmacies currently employ such initiatives to meet the complex medication needs of nursing facility patients, and the bill appropriately allows plan sponsors’ programs to distinguish between services provided in ambulatory and institutional settings.

Finally, the bill includes provisions to ensure that beneficiaries are guaranteed access to pharmacy services, including emergency services. The provisions are important to maintain the high standard of care for all beneficiaries, but particularly for patients in nursing facilities, who receive specialized pharmacy services 24 hours-a-day, seven days-a-week, through networks of long-term care pharmacies that contract with nursing facilities to meet their patients’ needs.

Mr. Speaker, I believe these long-term pharmacy provisions take a significant step toward ensuring that our nation’s most frail and elderly citizens will have affordable, appropriate prescription drugs and delivery services.

Mr. BASS. Mr. Speaker, as a member of the Energy and Commerce Committee, I am extremely pleased to have had the opportunity to develop a strong Medicare modernization package that will significantly improve this critical government program.

The seniors of New Hampshire have long clamored for a prescription drug benefit under Medicare, as is the case in the rest of the nation. I am pleased to represent those same seniors today as we pass this bill and take one more step closer toward our goal of creating a new and voluntary prescription drug benefit that makes lifesaving medications more accessible.

This benefit is the product of years of research, study, testimony, and compromise. I have no doubt whatsoever that each of us might wish for a slightly different version of this bill. We represent different regions with different demographics.

And, I am sure we all wish lifesaving drugs were more affordable for our families, friends, prescription drugs and delivery services. This is the fiscally responsible plan that will remain solvent in years to come, is easily accessible, and increasingly beneficial to seniors of all regions and means, was a daunting one.

Yet, the bill makes a number of Medicare improvements for care providers in New Hampshire. This proposal represents one of the most generous rural packages ever contemplated by the House. Notably, after several years of efforts on the part of the rural medical community, uniform standards for Medicare reimbursement will be established for rural and small urban facilities.

Beginning October 1, Medicare reimbursements to rural areas would finally mirror those for large urban ones. Having lamented for a
number of years over the inequity of this provi-
sion within the Medicare reimbursement sys-
tem, I am particularly pleased that this is being
addressed in the bill.

A drug benefit for seniors and a rejuvena-
tion of the Medicare system are essential to
seniors and their caretakers. The delivery of
Medicare has had a lot of criticism, and this
program was first conceived, and the pro-
gram ought to be modernized to reflect the in-
creases in medical technology and the utiliza-
tion of a wide range of care options.

As I have noted many times, no plan can be as
all-encompassing and immediately satis-
fying as we might prefer. However, this bill
puts the framework in place for a system that
can be adjusted and improved upon over time
and will directly and immediately help the pop-
ulation most in need.

I applaud all Members of the Energy and
Commerce Committee and the Members of
the Ways and Means Committee for the joint
work on this essential legislation. It is my hope
that upon completion of our floor vote today,
we will see this measure moved forward im-
mediately to conference with the Senate.

Mr. KROLLENBERG. Mr. Speaker, today
we have an opportunity to provide our seniors
with a new prescription drug benefit and im-
proved access to health care. It is a long over-
due step in updating and improving Medicare.
Today's legislation will provide health care for
those who need it most. Our 6.5 million low-
income seniors will receive a fully covered
premium and a cost sharing benefit when their
drug benefit switches from Medicaid to Medi-
care, paying no more than $2 per generic pre-
scription, or $5 for name brand drugs. This will
also save states about $6.8 billion a year in Medicaid costs.

It is imperative that Medicare advance with
technology. Prescription drugs are an increas-
ingly important part of modern medicine, help-
ing to relieve pain, cure disease, and enhance
the lives of millions of Americans. Adding a
drug benefit and updating how existing bene-
fits are provided will be a very significant ac-
complishment.

Mr. Speaker, I encourage my colleagues to
vote for this bill that helps our seniors by
providing a prescription drug benefit that they
deserve.

Mr. MOORE. Mr. Speaker, I rise today to
express my opposition to this legislation and
my support for the Blue Dog substitute, of-
ered by Rep. THOMPSON, which we have not
been allowed to debate on the House floor
today, despite support on both sides of the
Capitol.

We in Congress have been talking for years
now about the necessity of adding a prescrip-
tion drug benefit to Medicare. We know, as
seniors know, that this talk has been cheap
and it is imperative that a compromise be
reached this year. The Senate has been pro-
ceeding in a bipartisan way toward a com-
promise that adds a substantial, but not per-
fect, benefit to Medicare and protects the long-
term integrity of the social insurance program.
Instead of following the Senate’s lead and
working toward a compromise that will im-
prove Medicare, a wildly popular and success-
ful program, the House Republican leadership
has chosen, instead of add provisions to this
legislation that attacks the foundation of the
Medicare program. The bill does not include a
federal fallback if private plans choose not to
offer a benefit. The experience that my con-
stituents have had with Medicare+Choice
show that private health care plans are at best
an unstable partner for Medicare, and financial
analysts have consistently publicly questioned
whether "drug only" plans will ever be offered.
For these reasons, it is absolutely vital that
Medicare provide a viable and guaranteed fall-
bacK for Medicare beneficiaries.

Additionally, H.R. 1 would transform Medi-
care, beginning in 2010, from a defined-benefit
program to a defined-contribution program.
This provision would gradually shift enormous
costs to the senior citizens when they are sick
and most in need of care, and destroy the fabric
of this program that has served seniors well for
nearly 50 years.

The Senate has crafted legislation that has
broad support among Senators across the ide-
ological spectrum. This legislation has won the
support of both President Bush and Senator
TED KENNEDY. Together with Representative
THOMPSON and the Blue Dog Caucus, I am
supporting legislation that uses the framework
of the Senate compromise and improves on it,
making it a much stronger bill. The Thompson
plan builds on existing employer and Medicare
contributions to they will count toward the out-
of-pocket limit for catastrophic coverage, thus
giving employers an incentive to keep offering
retiree benefits. The substitute guarantees a
Medicare fall-back plan for all areas that do
not have private coverage. It also gives
relief to state Medicaid plans by making
Medicare the primary payer for all individuals
eligible for Medicare and Medicaid. Finally, the
Blue Dog substitute includes language that will
reduce the high cost of prescription drugs by
allowing Americans to reimport drugs from
Canada and speeding approval of generic
drugs.

The House bill falls short on several other
fronts as well. It ignores the needs of commu-
nity and teaching hospitals, meaning that hos-
pitals in my district stand to lose over $11 mil-
loon by now inflation updates. Kansas teach-
ing hospitals, like KU Med, would additionally
lose out to the tune of $3.9 million in 2003 and
$21 million over five years due to the Federal
Government’s failure to help pay for the ex-
cess costs. The Thompson substitute provides
an adequate inflation update for all hospitals. Finally, H.R. 1
would cut $16 billion over 10 years from oncology
services. Cancer patients all over the country
will have to pay for provisions in this bill that
sharply cut funding for cancer-fighting drugs
and allow Medicare to continue to underpay
for costs associated with providing chemother-
apy services.

I cannot support the Democratic substitute
because I believe that it is simply too expen-
sive. We must not recoup tax out because I believe that it is irresponsible for
Congress to run up bills for our children to
pay, and the Democratic substitute, although
a much more robust benefit for our seniors, is
simply more than our country can afford at this
time. The Senate bill and the Blue Dog sub-
stitute both have to the budget agreed to by
the House and Senate. Neither bill is perfect,
but I believe that the Thompson substitute
builds a strong foundation for a prescription
drug benefit on which we can build in future
years.

Mr. CAPUANO. Mr. Speaker, today we have
the opportunity to provide our seniors with a
real prescription drug benefit, but instead of
offering seniors the plan they deserve, we are
taking steps to dismantle a program that older
Americans have known and trusted for 38
years.

The Republican plan before us today fails to
offer the types of guarantees that our seniors
need and deserve. There is no defined benefit
and no standard premium. So when my sen-
iors ask how much their premiums will be or
how much their drugs will cost, I cannot an-
swer them. This is unacceptable.

This bill allows private insurance companies
to decide premiums, prescribe benefits, and
coverage benefits and even where coverage will
be offered. This proposal threatens to dis-
mantle Medicare and replace it with private
health insurance coverage for all seniors. This
is precisely the problem many seniors face—
they cannot afford private insurance, and de-
pend on Medicare.

This bill also provides additional funding for
rural hospitals, but not urban teaching hos-
itals. This is a serious oversight. Urban
teaching hospitals are facing incredible budget
shortfalls. They play a critical role in training
tomorrow’s physicians, and their needs must
also be addressed. If the Federal Government
is going to offer additional funding to some
hospitals, it must offer additional funding to
urban teaching hospitals.

The Federal Government has a responsi-
bility to ensure that Americans who contribute
to the Medicare program during their working
years will have access to dependable, equi-
table, and affordable health coverage. The
Democratic substitute does just that—it lowers
drug prices, guarantees coverage and enables
seniors to get their medicines at the pharmacy
of their choice. The Rangel/Dingell substitute
addresses my concerns more effectively and I
will strongly support it.

Mr. LEACH. Mr. Speaker, seldom has there
been a more important bill for the State of
Iowa.

On the one hand, this legislation provides
for greater equity in Medicare reimbursement
which will bring millions of additional dollars
to the state and help defray some of the costs
of healthcare providers from rural counties.

In addition, the burden of the bill is about
providing voluntary prescription drug coverage
to Medicare eligible individuals. There is a con-
sensus among our colleagues that it is far too
expensive, and a liberal critique that it is not
generous enough. Both philosophical perspec-
tives have a degree of validity, but the big pic-
ture is that Congress is moving in a direction
of providing health security for millions of citi-
zens. Low income individuals will, for the most
part, be provided full comprehensive prescrip-
tion drug coverage. Higher income citizens
on a sliding scale will be provided partial cov-
ervation and all citizens will be provided cov-
erage for catastrophic expenses.

There will be a cost to society in providing
these benefits but the benefits far outweigh
the costs. There may be better approaches
that can be envisioned now or developed
later, but this is the only framework approach
that has a chance of receiving majority sup-
sport in both the House and Senate. Without a
bipartisan approach, it may not be enough and
it may be too def-

fered in implementation but it nevertheless
marks an important first step to meeting the
most challenging need of many senior citi-
zens.

Ms. DEGETTE. Mr. Speaker, I want to high-
light a piece of the Dingell/Rangel substitute
that pertains to Disproportionate Share Hos-
itals.
This was an amendment I offered in the Energy & Commerce Committee and I understand that since our mark-up the DSH allocation has been increased and I want to commend this action. I know there is real bipartisan support on this issue and I want to just reiterate how important it is that we get funding to our DSH hospitals.

The provision in the substitute would give DSH hospitals a large portion of the funding that has been cut in the past year. It would expend a billion dollars in FY '03 and then adjust payments in future years to ensure that our vital DSH hospitals do not go bankrupt.

The reason it is so important that this money is available next year is that our DSH hospitals have already suffered a cut of a billion dollars in the past year and now are in such bad shape financially, if we help them in driblets and drabs than many of them won't be around ten years from now.

There are public hospitals who are currently planning to make cuts of 25 percent next year in order to try to stay afloat.

Mr. Speaker, our public hospitals cannot afford the cuts they are in real danger of losing numerous DSH hospitals over the next few years if we do not assist them right now.

This provision also helps the low-DSH hospitals which are the most strapped of all. Eighteen states have low DSH hospitals due to high costs and the hospitals that were basically frozen in place at a certain point.

These low-DSH states have been struggling for years with their Medicaid payments and they are currently held to only 1 percent of their Medicaid expenditures. My amendment, which accomplishes the same thing that a bill Rep. HEATHER WILSON introduced, would raise this to 3 percent which would help these states considerably.

While low-DSH states have been dealing with this situation for years, recently it has gotten much worse. The pressure on these hospitals has increased due to numerous factors such as increasing numbers of the uninsured, increasing numbers of Medicaid patients, the extreme situation so many states are in terms of budget crises.

The fact of the matter is that DSH hospitals need help and need help now. They can't wait and we need to rectify this situation while the DSH hospitals are still around to help our most vulnerable citizens.

Mr. DeLAURO. Mr. Speaker, in my 13 years in Congress, this House has sometimes risen to the occasion on matters of great national importance. My very first vote on the first Gulf War followed days of debate in which Members stated their heartfelt views on the prospect of war. After September 11th, we came together as Republicans—men and women, men and women—and we stood behind our President.

And I assure you when they find out we are doing nothing to hold down the excessive profiteering of the pharmaceutical companies, they are going to be angry. When seniors find out that their coverage essentially stops during mid-winter while they still have to pay premiums, they are not only going to be confused, they are going to feel utterly betrayed.

Mr. Speaker, we must provide a meaningful drug plan with guaranteed, defined benefits—with no gaps and no doughnut holes. We should support proposals that the Secretary of Health and Human Services—HHS—will provide better coverage for seniors than a reformed Medicare system . . . or if you think you can get all the drugs your doctor prescribed, including the most expensive, at your local pharmacy . . . Then you should be listening to that old country song by George Strait called "Ocean Front Property." It goes something like this:

As a freshman Member of Congress, I came here with a tremendous sense of optimism. By nature, I am an eternal optimist. But I am no fool, and the American people shouldn't be fooled either. Unfortunately, that is exactly what the Republicans are trying to do with their sham Prescription Drug bill.

If you believe the Republican bill solves the prescription drug crisis facing our seniors . . . If you think that seniors will get the medications they need, at a price they can afford . . . If you believe private insurance companies—the same people who brought you HMOs—will provide better coverage for seniors than a reformed Medicare system . . . or if you think you can get all the drugs your doctor prescribed, including the most expensive, at your local pharmacy . . . Then you should be listening to that old country song by George Strait called "Ocean Front Property."
Mr. JANKLOW. Mr. Speaker, I would like to submit the following letter to the Congressional Record.

Dear Speaker Hastert:

We urge you to pass legislation as part of Medicare reform that will improve the Drug Price Competition Act and Patent Term Restoration Act, and the patent listing requirements under the Federal Food Drug, and Cosmetic Act (FFDCA).

States spend billions of dollars annually and provide prescription medicine to residents, state employees, and retirees. Tax payers are forced to pay hundreds of millions of dollars in excess costs for the medicine because of loopholes in the Hatch-Waxman Act that restrict timely access to lower-cost generics and biologics. As a result, BAM members, including states, companies, and labor groups, support changes to the Hatch-Waxman Act that will provide greater pharmaceutical competition and more timely access to generic.

Bipartisan legislation passed by the Senate last week will provide all purchasers with greater access to generics, and will produce billions of dollars in savings for federal and state programs. We urge the House to adopt similar legislation as part of the effort by Congress to add a prescription drug benefit to Medicare, and urge you to resist changes or amendments that would weaken the most important cost-savings provisions in the Senate bill.

Specifically, BAM supports the proposed limit of one 30-month stay against FDA approval of generics, as well as provisions that provide for late entry patents—those filed after generic applications are submitted—to obtain additional stays. Litigation under the Hatch-Waxman Act is increased, and a bill that requires patentees that have been listed after the filing of generic applications, resulting in the need for legislation to restrict the use of 30-month stays to only those patents listed in the Orange Book prior to the filing of related generic applications. We also support changes to provisions in the law that allow drug manufacturers to intentionally contaminate their products. As a result, consumers and institutional purchasers have no standing under current law to challenge abusive listing. As a result, all purchasers have been forced to buy expensive drugs that are more expensive than necessary for products that should have faced more timely competition from generics. We support efforts to ensure generic manufacturers will be provided with the most effective avenues available for relief from unlawful listings.

BAM is committed to working with all members of Congress to restore balance to the Hatch-Waxman Act and improve pharmaceutical competition. We look forward to assisting your efforts.

Sincerely,

Governor Bob Wise, West Virginia,
Governor Brad Henry, Oklahoma,
Governor Bob Holden, Missouri,
Governor Ronnie Musgrove, Mississippi,
Governor Thomas Vilsack, Iowa.

Mr. ROGERS of Alabama. Mr. Speaker, one of the promises I made when I came to Washington was to improve the lives of East Alabama seniors. Unlike retirees in our country’s metropolitan areas, the seniors of the Third District face far greater challenges.

For starters, most Third District seniors lives in rural areas with few choices in health care providers. This undoubtedly means higher health costs and fewer choices when it comes to doctors, and higher out-of-pocket expenses for covering the same level of basic medical needs.

Part of the problem, Mr. Speaker, is Medicare does not fairly and adequately reimburse doctors for their services. This is not fair, especially when retirees just across the Georgia border have far better access to doctors who are reimbursed by Medicare at higher rates. Seniors should not be penalized just because they live in rural areas.

But assuming we fix the reimbursement problem, this still leaves Medicare as a program designed for the 1960s, yet providing care in 2003. That’s why I’m pleased to be in the House today to offer my full support for adding a prescription drug benefit under Medicare.

Earlier this year, Speaker HASTERT appointed me to his Prescription Drug Action Team to help craft a prescription drug benefit for Medicare. I’ve taken this responsibility around the Third District to talk to doctors, and describe what they think this benefit should do, and how it should be designed.

First and foremost, we must reduce the costs of prescription drugs. Modern medicine relies on these life-saving drugs more than ever, and doctors show no signs of slowing the expected growth in prescriptions. But with Alabama seniors now paying an average of $1,200 per year for prescriptions, these costs are getting out of hand.

Consider seniors on fixed incomes, Mr. Speaker. These Alabamians, already strapped with monthly bills, now face the costs of prescriptions rising beyond their means. We’ve already seen prescription drugs double or even triple in cost over the years. What will these seniors do when these drugs are priced out of reach? Will they be faced with filling these seniors do when these drugs are priced out of reach? Will they be faced with filling their medicine cabinet or their pantry?

Today, Mr. Speaker, I urge my colleagues not to support H.R. 1. Let’s tell the Republicans don’t try to sell seniors something they don’t want.

Mr. Speaker, I’m proud to be in this House today and have the chance to improve the lives of Alabama’s seniors. I will continue to work with my colleagues on both sides of the aisle, as well as those in the Senate, to help pass this important legislation now, and send it to the White House for President Bush to sign into law.

Mr. TAUZIN. Mr. Speaker, I yield back the balance of my time. The SPEAKER pro tempore (Mr. HASTINGS of Washington). All time for general debate has expired.

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on H.R. 1.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. RANGLER:

Mr. RANGLER. Mr. Chairman, I offer an amendment in the nature of a substitute.

The SPEAKER pro tempore. The Clerk will designate an amendment in the nature of a substitute.

The text of the amendment in the nature of a substitute is as follows:

Amendment in the nature of a substitute offered by Mr. RANGLER:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Medicare Prescription Drug and Modernization Act of 2003”.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or reenacting a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

Sec. 101. Voluntary medicare outpatient prescription medicine program.

Sec. 102. Medicare prescription drug benefit for the aged and disabled. This Act is a perfect bill, but it is a good bill. The legislation helps Alabama’s seniors receive better health care under Medicare and provides immediate relief from high prescription drug costs. President Bush supports it, and is ready to sign this bill should the House and Senate pass it.
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Sec. 933. Revisions to Medicare appeals process.

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Sec. 935. Recovery of overpayments.

Sec. 936. Provider enrollment process; right of appeal.

Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.

Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.

Subtitle V—Miscellaneous Provisions

Sec. 941. Policy development regarding evaluation and management (E & M) payment of guidelines.

Sec. 942. Improvement in oversight of technology and coverage.

Sec. 934. Treatment of hospitals for certain services under Medicare secondary payer (MSP) provisions.

Sec. 945. EMTALA improvements.

Sec. 946. Emergency medical treatment and active labor act (EMTALA) technical advisory group.

Sec. 947. Authorization of use of arrangements to provide core hospice services in certain circumstances.

Sec. 948. BIPA-related technical amendments and corrections.

Sec. 949. Conforming authority to waive a partial region determined appropriate by the Secretary, the Secretary may—

Title XI—Access to Affordable Pharmaceuticals

Sec. 1001. Importation of prescription drugs.

Title XII—Access to Affordable Medicines

Sec. 1010. Short title.

Sec. 1102. 30-month stay-of-effectiveness period.

Sec. 1103. Forfeiture of 180-day exclusivity period.

Sec. 1104. Bioavailability and bioequivalence.

Sec. 1105. Reforming the patent test for infringement.

Sec. 1106. Conforming amendments.

Title I—Medicare Prescription Medicine Benefit

Sec. 101. Voluntary Medicare outpatient prescription medicine program.

(a) In general.—Title XVIII (42 U.S.C. 1395 et seq.) is amended—

(1) redesignating section 1859 and part D as section 1859a and part E, respectively; and

(2) by inserting after part C the following new part:

PART D—Voluntary Prescription Medicine Benefit for the Aged and Disabled

"MEDICARE OUTPATIENT PRESCRIPTION MEDICINE BENEFIT"

"Sec. 1859a. (a) Authority to Negotiate Prices with Manufacturers.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and containing costs under this part, negotiate contracts with manufacturers of covered outpatient prescription medicines that provide for the maximum prices that may be charged to individuals enrolled under this part by participating pharmacies for dispensing such medicines to such individuals.

(b) Promotion of Breakthrough Medicines.—In conducting negotiations with manufacturers under this part, the Secretary shall take into account the goal of promoting the development of breakthrough medicines (as defined in section 1859m(b)).

"(c) Contractor Authority.—

(i) In general.—The Secretary is responsible for the administration of this part and shall enter into contracts with appropriate pharmacy contractors on a national or regional basis to administer the benefits under this part.

(ii) Procedures.—The Secretary shall establish procedures under which the Secretary—

(1) accepts bids submitted by entities to serve as contractors under this part in a region or on a national basis;

(2) awards contracts to such contractors to administer benefits under this part to eligible beneficiaries in the region or on a national basis; and

(3) provides for the termination (and non-renewal) of a contract in the case of a contractor’s failure to meet the requirements of the contract and this part.

(iii) Competitive Procedures.—Competitive procedures (as defined in section 45C of the Office of the Minority Health Policy Act (41 U.S.C. 403(5))) shall be used to enter into contracts under this part.

(iv) Terms and Conditions.—Such contracts shall have such terms and conditions as the Secretary shall specify and shall be for such terms (of at least 5 years, but not to exceed 5 years) as the Secretary shall specify consistent with this part.

(v) Use of Pharmacy Contractors in Price Negotiations.—Such contracts shall require the contractor involved to negotiate contracts with manufacturers that provide for maximum prices for covered outpatient prescription medicines that are lower than the maximum prices negotiated under section 1859a(a), applicable. The price reductions shall be passed on to eligible beneficiaries and the Secretary shall hold the contractor accountable for meeting performance requirements with respect to price reductions and limiting price increases.

(vi) Area for Contracts.—

(A) Regional Basis.—

(i) In general.—Except as provided in clause (ii) and subject to subparagraph (B), the contract entered into between the Secretary and a pharmacy contractor shall require the contractor to administer the benefits under this part in a region determined by the Secretary under subparagraph (B) or on a national basis.

(ii) Partial Regional Basis.—

(i) In general.—If determined appropriate by the Secretary, the Secretary may permit the benefits to be administered in a partial region determined appropriate by the Secretary.

(ii) Requirements.—If the Secretary permits administration pursuant to subparagraph (i), the partial region in which administration is effected is no smaller than a State and is at least the size of the commercial service area of the contractor for that area.

(ii) In general.—In determining regions for contracts under this part, the Secretary shall—

(I) take into account the number of individuals enrolled under this part in an area in order to encourage participation by pharmacy contractors; and

(II) ensure that there are at least 10 different regions in the United States.

(ii) No Administrative or Judicial Review.—The determination of appropriate regions under this paragraph shall not be subject to administrative or judicial review.

(7) Submission of Bids.—

(i) In General.—Subject to subparagraph (B), each entity desiring to serve as a pharmacy contractor under this part in an area shall submit a bid with respect to such area to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(ii) Bid that Covers Multiple Areas.—The Secretary shall permit an entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

(B) Required Information.—The bids described in subparagraph (A) shall contain—

(i) a proposal for the estimated prices of covered outpatient prescription medicines and the projected annual increases in such prices, including the additional reduction in price negotiated below the Secretary’s maximum price and differentials between preferred and nonpreferred prices, if applicable;

(ii) a statement regarding the amount that the entity will charge the Secretary for administering the benefits under the contract;

(iii) a statement regarding whether the entity will reduce the applicable coinsurance percentage, pursuant to subsection 1859(a)(1)(A) and if so, the amount of such reduction and how such reduction is tied to performance requirements described in subsection (c)(4)(A)(ii);

(iv) a detailed description of the performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(3)(A)(ii); and

(v) a detailed description of access to pharmacy services provided by the entity, including information regarding whether the pharmacy contractor is a part of the pharmacy network, and, if so, how the pharmacy contractor will ensure access to pharmacies that choose to be outside of that network, and whether there will be increased cost-sharing for beneficiaries if they obtain medicines at such pharmacies;

(vi) a detailed description of the procedures and standards the entity will use for—

(I) selecting preferred prescription medicines; and

(II) determining when and how often the list of preferred prescription medicines should be modified;

(vii) a detailed description of any ownership or shared financial interests with pharmaceutical manufacturers, pharmacies, and other entities involved in the administration or delivery of benefits under this part as proposed in the bid;

(viii) a detailed description of the entity’s estimated marketing and advertising expenditures related to enrollment and retaining eligible beneficiaries; and

(ix) such other information that the Secretary determines is necessary in order to carry out the requirements of this part.
The procedures under clause (vi) shall include the use of a pharmaceutical and therapeutics committee the members of which include practicing pharmacists.

The Secretary shall, consistent with the requirements of this part and the goals of providing quality and avoiding over-utilization, determine the number of pharmacy contractors for which the Secretary may contract. If an administrator of the Secretary awards a contract to a pharmacy contractor submitting a bid that meets the minimum standards specified under this part and by the Secretary.

The Secretary shall develop procedures to ensure that each eligible beneficiary enrolled under this part that resides in an area that is not covered by any pharmacy network shall have guaranteed access to the full range of pharmacies under this part, including through the use of a preferred pharmacy network to deliver the extended coverage required under clause (i).

The pharmacy contractor shall coordinate with State prescription medicine programs, other pharmacy contractors, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specifically authorize.

The pharmacy contractor shall maintain adequate records to ensure the appropriateness of prescription medicine dispensed, and ensure that participating pharmacists, physicians, and enrollees regard—

(i) instances or patterns concerning the unnecessary or inappropriate prescribing or dispensing of covered outpatient prescription medicines;

(ii) instances or patterns of standard care.

The pharmacy contractor shall provide for on-line prospective review of claims, access to pertinent pharmacy data, and on-line rejection requests to ensure the appropriateness of any claims submitted. The pharmacy contractor shall provide on-line prospective review available 24 hours a day and 7 days a week in order to evaluate each prescription for medicine therapy problems due to duplication, interaction, or incorrect dosage or duration of therapy.

The pharmacy contractor shall ensure that covered outpatient prescription medicines are accessible and convenient to eligible beneficiaries enrolled under this part who are administered by the pharmacy contractor, including by offering the services 24 hours a day and 7 days a week for emergencies.

The pharmacy contractor shall provide pharmacy services 24 hours a day and 7 days a week in order to evaluate each prescription for medicine therapy problems due to duplication, interaction, or incorrect dosage or duration of therapy.

The pharmacy contractor shall ensure that covered outpatient prescription medicines are accessible and convenient to eligible beneficiaries enrolled under this part who are administered by the pharmacy contractor, including by offering the services 24 hours a day and 7 days a week for emergencies.

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section 1851(h) (relating to marketing mate-
rial and application forms) with respect to this 
part in the same manner as such re-
quirements apply under part C, except that 
the standards relating to the time taken to answer 
member and pharmacy inquiries (written or by tele-
phone), the accuracy of responses, claims 
processing accuracy, online system availability, 
and other similar factors determined appropriate by the 
Secretary shall apply rules similar to the rules de-
scribed in or under this subsection.

(2) SPECIAL ENROLLMENT PERIODS— 
(A) INDIVIDUALS CURRENTLY COVERED.—In 
the case of physician an individual who satis-
ifies subsection (a) is enrolled in a group 
health plan that provides outpatient pre-
sic medicine coverage other than by 
contractually with the pharmacy contractor.

(ii) the pharmacy does not charge (or col-
gate or, if lower, negotiated under subsection 
(4)(a)(5) (or, if less, the retail price for the med-
icine involved) with respect to such medicine plus a reasonable dispensing fee determined 
contractually with the pharmacy contractor.

(iii) The pharmacy does not charge (or col-
gate) for, or, if lower, negotiated under subsection 
(4)(a)(5) (or, if less, the retail price for the med-
icine involved) with respect to such medicine plus a reasonable dispensing fee determined 
contractually with the pharmacy contractor.

(iv) The pharmacy does not charge (or col-
gate) a pharmacy contractor specifies under this section.

(3) SPECIAL ENROLLMENT PERIODS— 
(A) INDIVIDUALS CURRENTLY COVERED.—In 
the case of an individual who satisfies sub-
section (a) as of November 1, 2005, the initial 
general enrollment period shall begin on 
August 1, 2005, and shall end on March 1, 2006.

(B) INDIVIDUAL COVERED IN FUTURE.—In 
the case of an individual who satisfies sub-
section (a) or after November 1, 2005, the 
individual's initial enrollment period shall begin on the first day of the third 
month before the month in which such indi-
vidual satisfies such paragraph and shall end seven months later. The Secretary 
shall apply rules similar to the rule de-
scribed in the second sentence of section 1873(d).

(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PREMIUM PENALTY).— 
(A) EMPLOYER COVERAGE AT TIME OF IN-
TIAL GENERAL ENROLLMENT PERIOD—In the 
case of an individual who—
(i) is at the time the individual first satis-
ifies subsection (a) is enrolled in a group 
health plan (including continuation cov-
verage) that provides outpatient prescription 
medicine coverage by reason of the individ-
ual's own employment status, or, (or, in the case of continuation coverage, former) 
employment status, and 
(ii) has elected not to enroll (or to be 
deemed enrolled) under this subsection dur-
ing the individual's initial enrollment pe-
riod, there shall be a special enrollment period of six months beginning with the first month 
that includes the date of the individual's (or individual's spouse's) retirement from or termi-
nation of current employment status with the employer that satisfies the plan, or, in 
the case of continuation coverage, that in-
cludes the date of termination of such cov-
verage, or that includes the date the plan sub-
stitutes outpatient prescription medicine coverage.

(B) DROPPING OF RETIREE PRESCRIPTION MEDICINE COVERAGE.—In the case of an indi-

(ii) at the time the individual first satis-
ifies subsection (a) is enrolled in a group 
health plan that provides outpatient pre-
sic medicine coverage by reason of the individ-
ual's own employment status, or, (or, in the case of continuation coverage, former) 
employment status, and
(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual’s initial enrollment period, there shall be a special enrollment period of 6 months beginning with the first month that includes the date that the plan substantially terminates outpatient prescription medicine coverage and ending 6 months later.

(C) LOSS OF MEDICARE-CHOICE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who is enrolled under this part and is enrolled in a Medicare-Choice plan under part C, the individual shall be provided the benefits under this part through such plan and not through payment under this part.

(D) LATE ENROLLMENT PENALTIES; PAYMENT OF PREMIUMS.—

(1) IN GENERAL.—In the case of a late enrollment described in subsection (b)(4), subject to the succeeding provisions of this paragraph, the Secretary shall establish procedures for increasing the amount of the monthly premium under this part applicable to such enrollee by an amount that the Secretary determines is actuarially sound for each such period.

(ii) periods taken into account.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account months of lapsed coverage in a manner comparable to that applicable under the second sentence of section 1859B(b).

(C) PERIODS NOT TAKEN INTO ACCOUNT.—

(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), there shall not be taken into account months for which the enrollee can demonstrate that the enrollee was covered under a group health plan that provides coverage for prescription medicines whose actuarial value (as defined by the Secretary) to the enrollee equals or exceeds the actuarial value of the benefits provided in individual enrollment in the outpatient prescription medicine benefit program under this part.

(ii) application.—This subparagraph shall only apply to a coverage period for which occurs before the end of the 60-day period that begins on the first day of the month which includes the date on which the plan terminates or reduces its service area (in a manner that results in termination of enrollment), ceases to provide, or reduces the value of the prescription medicine coverage under such plan to below the value of the coverage provided under the program under this part.

(2) INCORPORATION OF PREMIUM PAYMENT AND PRESCRIPTION BENEFITS INTO 12-MONTH PERIODS.—The provisions of sections 1859B(d)(1) and 1844(a)(1) shall apply to enrollees under this part in the same manner as they apply to individuals who are enrolled under part B. For purposes of this subsection, any reference in a section referred to in a previous subsection to the Federal Supplementary Medical Insurance Trust Fund is deemed a reference to the Federal Medicare Prescription Medicine Trust Fund.

(3) ELECTION OF PHARMACY CONTRACTOR TO ADMINISTER BENEFITS.—The Secretary shall establish a program whereby each individual enrolled under this part and residing in a region may elect the pharmacy contractor that will administer the benefits under this part with respect to the individual. Such program shall permit the individual to make an initial election and to exchange such an election on at least an annual basis and under such other circumstances as the Secretary shall specify.

(4) COUNSELING AND INFORMATION.—The Secretary shall provide for the application of provisions under this subsection similar to the provisions in section 1885(b).

(5) LIMITATION ON COST-SHARING FOR PART B PRESCRIPTION MEDICINES.—

(i) in general.—For purposes of this part, the term ‘cost-sharing’ means—

(ii) out-of-pocket expenses for outpatient prescription medicines with respect to which benefits are payable under part B.

(iii) cost-sharing under subsections (c)(3)(B) and (c)(3)(C)(i).

(6) COVERED OUTPATIENT PRESCRIPTION MEDICINE BENEFITS.—

(i) in general.—Except as provided in paragraph (2), for purposes of this part the term ‘covered outpatient prescription medicine’ means any of the following products:

(A) A medicine which may be dispensed only upon prescription, and which is effective and safe and effective as a prescription medicine under section 505 of the Federal Food, Drug, and Cosmetic Act.

(B) A biological product which—

(i) is commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 which is identical, similar, or related (within the meaning of section 310(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (ii) which has not been the subject of a final determination by the Secretary that it is a ‘new drug’ (within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act) on a proposed order of the Secretary that it is a ‘new drug’ (within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(ii) which is described in section 102(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (ii) for which the Secretary has not issued a notice of noncompliance (as defined in section 310(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (ii) which has not been the subject of a final determination by the Secretary that it is a ‘new drug’ (within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act) on a proposed order of the Secretary to withdraw approval of an application for such a medicine, or for which the Secretary has determined that the medicine is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

(B) A biological product which—

(i) is licensed under section 351 of the Public Health Service Act; and

(ii) is produced at an establishment licensed under such section to produce such product.

(C) Insulin approved under appropriate Federal law, and needles, syringes, and disposable pumps for the administration of such insulin.

(D) A prescribed medicine or biological product that would meet the requirements of subparagraph (A) or (B) but that is available over-the-counter in addition to being available upon prescription, but only if the particular dosage form or strength prescribed and required for the individual is not available over-the-counter.

(E) Smoking cessation agents (as specified by the Secretary).
"(2) EXCLUSION.—The term ‘covered outpatient prescription medicine’ does not include— 

(A) medicines or classes of medicines, or their equivalents, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), under paragraph (1)(D) or (1)(E), any product which may be distributed to individuals without a prescription; 

(C) any product when furnished as part of, or as incident to, a diagnostic service or any other item or service for which payment may be made under this title; or 

(D) any product that is covered under part B of this title.

"(c) PAYMENT OF BENEFITS.— 

"(1) COVERED OUTPATIENT PRESCRIPTION MEDICINES.—There shall be paid from the Federal Medicare Prescription Medicine Trust Fund, in the case of each enrollee who incurs expenses for medicines with respect to which benefits are payable under this part under subsection (a)(1), amounts equal to the sum of— 

(A) the price for which the medicine is made available under this part (consistent with sections 1859A and 1859B), reduced by any applicable cost-sharing under paragraphs (2) and (3); and 

(B) a reasonable dispensing fee. 

The price under subparagraph (A) shall in no case exceed the retail price for the medicine involved. 

"(2) DEDUCTIBLE.—The amount of payment under paragraph (1) for expenses incurred in a year shall be reduced by an annual deductible equal to the amount specified in section 1859(2) (subject to adjustment under paragraph (b)). Only expenses for countable cost-sharing (as defined in subsection (a)(2)(B)) shall be taken into account in applying this paragraph. 

"(3) COINSURANCE.— 

(A) IN GENERAL.—The amount of payment under paragraph (1) for expenses incurred in a year shall be further reduced (subject to the stop-loss limit under paragraph (4)) by coinsurance as provided under this paragraph. 

(B) PREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a preferred medicine (including a medicine treated as a preferred medicine under paragraph (5)), is equal to 20 percent of the price applicable under paragraph (1)(A) (or such lower percentage as may be provided for under section 1859E(a)(1)(A)(i)). In this part, the term ‘preferred medicine’ means, with respect to medicines classified within a therapeutic class, those medicines which have been designated as a preferred medicine by the Secretary or the pharmacy contractor involved with respect to that class and (in the case of a nongeneric medicine) with respect to which a contract has been negotiated under this part. 

(C) NONPREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a nonpreferred medicine that is not treated as a preferred medicine under paragraph (5) is equal to the sum of— 

(i) the price of such lowest price preferred medicine; 

(ii) no coinsurance once out-of-pocket expenditures equal stop-loss limit. 

Once an enrollee has incurred an out-of-pocket cost-sharing under paragraph (3) (including cost-sharing under part B attributable to outpatient prescription drugs or biologicals) and the Stop-Loss Limit under section 1859(4) (subject to adjustment under paragraph (b)) for expenses incurred in a year— 

(A) there shall be no coinsurance under paragraph (3); or 

(B) there shall be no coinsurance under part B for expenses incurred in the year involved; and 

(C) if the enrollee’s share of the stop-loss limit under paragraph (3) for expenses incurred in a year exceeds 

(iii) the price of such lowest price preferred medicine. 

"(d) PROVISION OF BENEFITS.— 

"(1) IN GENERAL.—With respect to expenses incurred in a year after 2006— 

(i) the deductible under paragraph (2) is equal to the deductible determined under paragraph (2)(A) for the previous year by the Secretary; and 

(ii) the stop-loss limit under paragraph (3) is equal to the stop-loss limit determined under paragraph (3) for the previous year increased by such percentage increase. 

The Secretary shall adjust such percentage increase in subsequent years to take into account misestimations made of the per capita program expenditures under clauses (i) and (ii) in previous years. Any increase under this subparagraph that is not a multiple of $20 shall be rounded to the nearest multiple of $10. 

"(e) ESTIMATION OF INCREASE IN PER CAPITA PROGRAM EXPENDITURES.—The Secretary shall adjust such percentage increase in the beginning of each year (beginning with 2007) estimate the percentage increase in average per capita aggregate expenditures from the Federal Medicare Prescription Medicine Trust Fund for the year involved compared to the previous year. Any increase under this subparagraph that is not a multiple of $1 shall be rounded to the nearest multiple of $1. 

"(f) COINSURANCE.— 

"(1) MONTHLY PREMIUM RATE IN 2006.—The monthly premium rate in 2006 for prescription medicine benefits under this part is the amount specified in section 1859A. 

"(2) INFLATION ADJUSTMENT FOR SUBSEQUENT YEARS.—The monthly premium rate for a year after 2006 for prescription medicine benefits under this part is equal to the monthly premium rate for the previous year under this subsection increased by the percentage increase in prescription expenditures (as estimated in advance for the year involved under subsection (c)(8)(B)). The Secretary shall adjust such percentage increase in subsequent years to take into account misestimations made of the per capita program expenditures under the previous sentence in previous years. Any increase under this subparagraph that is not a multiple of $1 shall be rounded to the nearest multiple of $1. 

"(g) ADMINISTRATION; QUALITY ASSURANCE 

"(Sec. 1859E. (a) RULES RELATING TO PROVISION OF BENEFITS.— 

"(1) PROVISION OF BENEFITS.— 

(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through contracts with pharmacy contractors) shall ensure that benefits are provided appropriately and efficiently, to the extent that the beneficiaries are reasonable compared to the previous year. 

"(B) TRANSFER OF FUNDS TO COVER COSTS OF PART B PRESCRIPTION MEDICINE CATASTROPHE BENEFIT.—With respect to benefits described in subparagraph (A) that are transferred from the Federal Medicare Prescription Medicine Trust Fund to the Federal Supplementary Medical Insurance Trust Fund amounts equivalent to the elimination of cost-sharing described in such subsection. 

"(C) PERMITTING APPLICATION UNDER PART B OF NEGOTIATED PRICES.—For purposes of negotiating payments under Part B of this title for medicines that would be covered outpatient prescription medicines but for the exclusion under subparagraph (B) or (C) of section 1859(b), the Secretary shall apply the part B payment basis or the default basis, as appropriate, as provided in section 1859(b), if it results in a lower cost to the program. 

"(III) methods to reduce medication errors and encourage appropriate use of medications; and 

(c) enrolling pharmacy contractors, as approved by the Secretary, to make exceptions to section 1859(c)(3)(C) (relating to cost-sharing for non-preferred medicines) to the extent that the contractor determines as appropriate for the payment under section 1859(c)(1) does not exceed $0.
"(B) CONSTRUCTION.—Nothing in this subsection shall be construed to prevent the Secretary (directly or through the contracts with pharmacy contractors) from using incentives to enroll enrollees to select generic or other cost-effective medicines, so long as—

(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund; and

(ii) a beneficiary’s coinsurance shall be no greater than 20 percent in the case of a preferred medicine (including a nonpreferred medicine treated as a preferred medicine under section 1895B(e)(2))."

"(2) CONSTRUCTION.—Nothing in this part shall preclude the Secretary or a pharmacy contractor from—

(A) educating prescribing providers, pharmacists, and enrollees about medical and cost benefits of preferred medicines; 

(B) requesting prescribing providers to consider nonpreferred medicines prior to dispensing of a nonpreferred medicine, as long as such request does not unduly delay the provision of the medicine; 

(C) requesting pharmacy contractors to encourage enrollees under this part to select cost-effective medicines or less costly means of receiving or administering medicines, including the use of therapeutic interchange programs, disease management programs, and notification to the beneficiary that a more affordable medicine with equivalent effectiveness was not selected by the prescribing provider and a statement of the lost cost savings to the beneficiary; 

(D) using price negotiations to achieve reduced prices on covered outpatient prescription medicines, including new medicines, medicines for which there are few therapeutics, and medicines of particular clinical importance to individuals enrolled under this part; and

(E) utilizing information on medicine prices of OECD countries and of other payors in the United States in the negotiation of prices under this part.

"(b) REQUIREMENTS WITH RESPECT TO PREFFERED MEDICINES.—Negotiations of contracts with manufacturers with respect to coverage of outpatient prescription medicines under this part shall be conducted in a manner so that—

(A) there is at least a contract for a medicine in a therapeutic class negotiated by the Secretary in consultation with such Medicare Prescription Medicine Advisory Committee;

(B) if there is no more than 1 medicine available in a therapeutic class, there are contracts for at least 2 medicines within such class unless determined clinically inappropriate in accordance with standards established by the Secretary; and

(C) if there are more than 2 medicines available in a therapeutic class, there is a contract for each medicine in such therapeutic class negotiated by the Secretary in consultation with such Medicare Prescription Medicine Advisory Committee.

"(2) ANNUAL ASSURANCES AND NOTICE BEFORE TERMINATION.—The sponsor of the plan shall annually attest, and provide such assurances as the Secretary may require, that the coverage offered under the group health plan meets the requirements of this section and will continue to meet such requirements for the duration of the sponsor’s participation in the program under this section; and

(i) at least 120 days before terminating its plan, and

(ii) immediately upon determining that the actuarial value of the prescription medicine benefit under the plan falls below the actuarial value required under subsection (a).

"(3) BENEFICIARY INFORMATION.—The sponsor of the plan shall report to the Secretary, for each calendar quarter for which it seeks a contract under this section, the names and social security numbers of all enrollees described in subsection (a) covered during such quarter and the dates (if less than the full quarter) during which each such individual was covered.

"(4) AUDITS.—The sponsor or plan seeking payment under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription medicine coverage, the accuracy of payments made, and such other matters as may be appropriate.

"(c) PAYMENT.—

(1) IN GENERAL.—The sponsor of a group health plan that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made on a quarterly basis of the amount specified in paragraph (2) for each individual described in subsection (a) who during the quarter is covered under the plan and who was enrolled in the insurance program under this part.

"(2) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—The amount of the payment for a quarter is the amount specified in subsection (a), divided by the number of months in such quarter, multiplied by the number of days in such quarter.

(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly government contribution amount for a month in a year is equal to the amount by which—

(i) ⅔ of the average per capita aggregate expenditures, as estimated under section 1859B(b)(1)(B) for the year involved; decreases, as estimated under section 1859B(b)(1)(B) for the year involved; and

(ii) the monthly premium rate under section 1858(c)(b) for the month involved.

"(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary, through designee of the Inspector General, is authorized and directed to issue regulations establishing appropriate safeguards to prevent fraud and abuse under this part. Such safeguards, at a minimum, should include compliance programs, certification data, audits, and recordkeeping practices. In developing such regulations, the Secretary shall consult with the Attorney General and other law enforcement and regulatory agencies.

"(e) CONFIDENTIALITY.—The Secretary shall—

(B) guarantee that it will give notice to the Secretary of breaches of confidentiality.

"(f) REPORTING.—The Secretary shall report to the Inspector General, on a quarterly basis, any instances of fraud and abuse in connection with the operation of this part.
"(A) standards required of pharmacy contractors under section 189D(c)(5) for determining if a medicine is as effective for an enrollee or has a significant adverse effect on an enrollee as another medicine;" 
"(B) standards for—
(i) defining therapeutic classes;
(ii) adding new therapeutic classes;
(iii) assigning to such classes covered outpatient prescription medicines; and
(iv) identifying breakthrough medicines;
(C) procedures to evaluate the bids submitted by pharmacy contractors under this part;
(D) procedures for negotiations, and standards for entering into contracts, with manufacturers to identify covered medicines or classes of medicines where Secre-
tarial negotiation is most likely to yield savings under this part significantly above those that could be achieved by a pharmacy contractor; and
(E) procedures to ensure that pharmacy contractors with a contract under this part are in compliance with the requirements under this part.

For purposes of this part, a medicine is a 'breakthrough medicine' if the Secretary, in consultation with the Committee, determines it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality or disability, and that no other product is available to beneficiaries that achieves similar results for the same condition.

The Committee may consider cost-effectiveness when establishing standards for defining therapeutic classes and assigning drugs to such classes under subparagraph (B).

(2) Structure and Membership of the Committee.—
(1) Structure.—The Committee shall be composed of 19 members who shall be ap-
pointed by the Secretary.
(2) Membership.—
(A) In General.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judg-
ment, and shall be individuals who are, by reason of their education, experience, and att-
tainments, exceptionally qualified to per-
form the duties of members of the Com-
mittee.
(B) Specific Members.—Of the members ap-
pointed under paragraph (1)—
(i) 5 shall be chosen to represent prac-
ticing physicians, 2 of whom shall be gastro-
enterologists;
(ii) 2 shall be chosen to represent prac-
ticing nurse practitioners;
(iii) 4 shall be chosen to represent prac-
ticing pharmacists;
(iv) 1 shall be chosen to represent the Centers for Medicare & Medicaid Services;
(v) 4 shall be chosen to represent actuar-
ies, risk actuaries, demographers, researchers, and other appropriate experts;
(vi) 1 shall be chosen to represent emerg-
ning medicine technologies;
(vii) 5 shall be chosen to represent the Food and Drug Administration; and
(viii) 1 shall be chosen to represent indi-
viduals enrolled under this part.

(C) Terms of Appointment.—Each mem-
ber of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members ini-
tially appointed shall begin on January 1, 2005.

(D) Chairperson.—The Secretary shall designate the chairperson of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

(E) Committee Personnel Matters.—
(i) Compensation.—Each member of the Committee who is not an officer or employee of the Federal Government shall be com-
In paragraph (1) by striking "1859(b)" and inserting "1858(b)".

(2) Travel Expenses.—The members of the Committee shall be allowed travel exp-
enses, including subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes of business in the performance of services for the Com-
mittee.

(2) Staff.—The Committee may appoint sur-
veying personnel as the Committee considers appropriate.

(g) Operation of the Committee.—
(1) Meetings.—The Committee shall meet at the call of the Chairperson (after con-
sultation with the other members of the Committee) not less often than quarterly to consider a specific agenda of issues, as deter-
mined by the Chairperson after such con-
sideration.

(2) Quorum.—Ten members of the Com-
mittee shall constitute a quorum for pur-
poses of conducting business.

(h) Federal Advisory Committee Act.—
Section 14 of the Federal Advisory Com-
mittee Act (5 U.S.C. App.) shall not apply to the Committee.

(i) Transfer of Personnel, Resources, and Assets.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Com-
mittee of civil service personnel in the executive branch of the Department of Health and Human Services (including the Centers for Medicare & Medicaid Services), and such re-
sources and assets of the Department used in carrying out this title, as the Committee re-
quires.

(j) Authorization of Appropriations.—
There are appropriated such sums as may be necessary to carry out the purposes of this section.

(k) Application of General Exclusions from Coverage.—
(1) Application to Part D.—Section 1862(a) (42 U.S.C. 1395w–21(a)) is amended in the matter preceding subparagraph (C) by striking "part A or part B" and inserting "part A, B, or D".
(2) Prescription Medicines Not Excluded from Coverage if Appropriately Prescribed.—Section 1862(a)(1) (42 U.S.C. 1395w–21(a)(1)) is amended—
(A) in subparagraph (H), by striking "and" at the end;
(B) in subparagraph (I), by striking the semicolon at the end and inserting "; and";
(C) by adding at the end the following new subparagraph:
"(j) in the case of prescription medicines covered under part D, which are not pre-
scribed in accordance with such part;"
(D) conforming amendments.—(i) Part C of title XVIII is amended—
(A) in section 1851(a)(2)(B) (42 U.S.C. 1395w–21(a)(2)(B)), by inserting "1858(b)(3)" and inserting "1858(b)(3)";
(B) in section 1851(a)(2)(C) (42 U.S.C. 1395w–21(a)(2)(C)), by striking "1859(b)(2)" and inserting "1858(b)(2)";
(C) in section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)), by striking "1859(b)(3)" and inserting "1858(b)(3)";
(D) in section 1852(a)(2)(B) (42 U.S.C. 1395w–22(a)(2)(B)), by striking "1859(b)(3)" and inserting "1858(b)(3)"

(k) Application of Quality Standards.—
Section 1858(b)(3) (42 U.S.C. 1395w–22(b)(3)) is amended—
(1) by striking "the Secretary may conduct a survey of..." and inserting "the Secretary shall conduct a survey of...";
(2) by striking the period at the end of clause (xii) and inserting "; and";
(3) by striking clause (xii) and inserting clauses (xii) and (xiii) and clauses (xiv) and (xv); and
(4) by striking clause (xiii) and inserting clauses (xiii) and (xiv)

(l) Application of Child Planning Assistance Act.—
Section 1859(e)(4) (42 U.S.C. 1395w–23(e)(4)) is amended—
(1) by striking paragraph (b) and inserting paragraph (a) and (b) and (c), (d), and (e);
(2) by striking paragraph (c) and inserting paragraph (d) and (e); and
(3) by striking paragraph (d) and inserting paragraph (e)

(m) Payment for Prescription Medicine Coverage Options.—
(1) In General.—In the case of a Medicare+Choice plan that provides prescrip-
tion medicine benefits described in section 1851(a)(3)(A) (42 U.S.C. 1395w–23(a)(3)(A)) for purposes of coverage and payment and any reference in this section to the Federal Supple-
mentary Medical Insurance and Trust Fund shall be deemed, with respect to such benefits, to be a reference to the Federal Medicare Pre-
scription Medicine Trust Fund.

(2) Application of Quality Standards.—
Section 1858(h)(2)(B) (42 U.S.C. 1395w–22(b)(2)(B)) is amended—
(1) by striking paragraph (B); and
(2) by striking clause (ii) and inserting clause (i), and (j) and
(3) by striking clause (i) and inserting clause (i) and (j) and
(4) by striking paragraph (D) and inserting paragraph (E)

(n) Joint and Several Liability.—
Section 1859(b)(2)(D) (42 U.S.C. 1395w–23(b)(2)(D)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C)

(o) Determining Whether Medicare+Choice Plan Offers Equivalency.—
Section 1859(b)(3)(A) (42 U.S.C. 1395w–23(b)(3)(A)) is amended—
(1) by striking paragraph (A) and inserting paragraph (B) and
(2) by striking paragraph (B) and inserting paragraph (C)

(p) Definition of Eligible Individual.—
Section 1859(b)(3)(B) (42 U.S.C. 1395w–23(b)(3)(B)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C)

(q) Minimum Monthly Contribution.—
Section 1859(b)(3)(C) (42 U.S.C. 1395w–23(b)(3)(C)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C)

(r) Determining Whether Medicare+Choice Plan Offers Equivalency.—
Section 1859(b)(3)(D) (42 U.S.C. 1395w–23(b)(3)(D)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C) and
(2) by striking paragraph (C) and inserting paragraph (D)

(s) Determining Whether Medicare+Choice Plan Offers Equivalency.—
Section 1859(b)(3)(E) (42 U.S.C. 1395w–23(b)(3)(E)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C)

(t) Determining Whether Medicare+Choice Plan Offers Equivalency.—
Section 1859(b)(3)(F) (42 U.S.C. 1395w–23(b)(3)(F)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C) and
(2) by striking paragraph (C) and inserting paragraph (D)

(u) Determining Whether Medicare+Choice Plan Offers Equivalency.—
Section 1859(b)(3)(G) (42 U.S.C. 1395w–23(b)(3)(G)) is amended—
(1) by striking paragraph (B) and inserting paragraph (C) and
(2) by striking paragraph (C) and inserting paragraph (D)
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"(3) Risk Adjustment.—The Secretary shall establish a methodology for the adjustment of the payment amount under this subsection in a manner that takes into account the risk factors for the use of outpatient prescription medicines by Medicare+Choice enrollees. Such methodology shall be designed in a manner so that the total payments under part D of title XVIII under this subsection is not changed as a result of the application of such methodology."

PART D APPLICATION OF ADJUSTED COMMUNITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w-24) is amended by adding at the end the following:

"(i) SECTION 1854 AMENDMENTS.—(1) Section 1851 (42 U.S.C. 1395w-21) is amended—

(A) by striking "and" at the end of clause "; "B" and inserting "parts A, B, and D"; and

(B) in subsection (i) by inserting "(and, if applicable, part D)" after "parts A and B.

(2) Section 1852(a)(1)(A) (42 U.S.C. 1395w-22(d)(1)) is amended by inserting "(and under part D to individuals also enrolled under such part)" after "parts A and B".

(3) Section 1854(e) (42 U.S.C. 1395w-22(d)(1)) is amended—

(A) by striking "and" at the end of subparagraph (D);

(B) striking the period at the end of subparagraph (E) and inserting "; and"; and

(C) by adding at the end the following:

(F) the plan for part D benefits guarantees that all policies providing pre-scription medicine for an enrollee to the extent that it would be required to be covered under part D.

In carrying out subparagraph (F), a Medicare+Choice organization has the same authority to enter into contracts with respect to coverage of preferred medicines as the Secretary has under part D, but subject to an independent contractor appeal or other appeal process that would be applicable to determinations by such a pharmacy contractor consistent with section 1856(c)(1).

II. DECREASE IN COST-SHARING.—Section 1854(e) (42 U.S.C. 1395w-24(e)) is amended by adding at the end the following new paragraph:

"(5) LIMITATION ON COST-SHARING.—In no event may a Medicare+Choice organization include a requirement that an enrollee pay cost-sharing in excess of the cost-sharing otherwise permitted under part D."

SEC. 103. MEDIGAP REVISIONS.

(a) REQUIRED COVERAGE OF COVERED OUT-PATIENT PRESCRIPTION MEDICINES.—Section 1856(p)(2)(B) (42 U.S.C. 1395w-22(d)(1)) is amended by inserting before "and" at the end the following:

"including a requirement to add a separate regular section of the State legisla-ture."

SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME BENEFICIARIES.

(a) QMB COVERAGE OF PREMIUMS AND COST-SHARING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is amended—

(1) in subparagraph (A),

(A) by striking "and" at the end of clause (i),

(B) by adding "and" at the end of clause (ii), and

(C) by adding at the end the following new clause:

"(iii) premiums under section 1903(d);"

(2) in subparagraph (B), by inserting "and section 1903(d)" after "1913;" and

(3) in subparagraph (C), by striking "section 1903(d)" and inserting "section 1913(b), and section 1952(d)(2)."

(b) EXPANDED SLMB ELIGIBILITY.—Section 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amended—

(1) by striking "and" at the end of clause 

"(iv); and

(2) by adding "and" at the end of clause 

"(v); and

(3) by adding at the end the following new clause:

"(ii) for making medical assistance available for Medicare+Choice organizations that have medicaid cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) under section 1905(p)(3)(C) but otherwise permitted under part D of title XVIII, and the assistance for medicare costs described in section 1905(p)(3)(A)(iii) is reduced (on a sliding scale based on income) from 100 percent to 0 percent as the income increases from 100 percent to 125 percent of such poverty line;"
by adding at the end the following:

(i) The aggregate amount specified in this clause for—

(ii) 2006, is equal to $25,000,000 or

(ii) a subsequent year, is equal to the aggregate specified in this clause for the previous year increased by annual percentage increase specified in section 1855(d)(8)(B)(i) for the year involved.

(f) The Secretary shall submit to Congress a report on the application of this paragraph and may include in the report such recommendations as the Secretary deems appropriate.

(2) CONFORMING AMENDMENT.—Section 1102(h) (42 U.S.C. 1306(h)(2)) (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following:

"The previous sentence shall not apply to medicare cost-sharing relating to benefits under part D of title XVIII." (f) E FFECTIVE DATE.—The amendments made by this section apply to premium years beginning on or after January 1, 2006, and with regard to whether regulations to implement such amendments are promulgated by such date.

Sect. 165. EXPANDED MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1855(c) (42 U.S.C. 1395b–6(c)) is amended—

(A) in paragraph (1), by striking "17" and inserting "19";

(B) in paragraph (2)(B), by inserting "exerts in the area of pharmacology and prescription medicine benefit programs," after "other health professionals;" and

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of stage—

(i) The Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable to the low-income assistance eligibility and benefits offered under part D of title XVIII of the Social Security Act.

(ii) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

(iii) Representatives of Medicare-Medicaid eligible beneficiaries, as appointed by the Secretary.

(iv) Representatives of Medicare-Medicaid eligible beneficiaries, as appointed by the Secretary.

(v) Representatives of Medicare-Medicaid eligible beneficiaries, as appointed by the Secretary.

(vi) Representatives of Medicare-Medicaid eligible beneficiaries, as appointed by the Secretary.

(b) EXPANSION OF DUTIES.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended, in paragraph (1)(A), by inserting "(for a year before 2004)" after "multiplied"; and

(c) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under title XVIII who are enrolled under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan for the year were not adjusted to payments under section 1898(h).

(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under title XVIII who are enrolled under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan for the year were not adjusted to payments under section 1898(h).

(iii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under title XVIII who are enrolled under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan for the year were not adjusted to payments under section 1898(h).

(iv) CONFORMING AMENDMENT.—Section 1855(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended—

(A) in subparagraph (B)(iv), by striking "(before multiplying)"; and

(B) in paragraph (5), by inserting "who (with respect to determinations for 2004) are enrolled in a Medicare+Choice plan" after "the average number of Medicare beneficiaries".

(b) REVISION OF BLEND.—

(1) REVISION OF NATIONAL AVERAGE USED IN CALCULATION OF BLEND.—Section 1855(c)(6)(B)(i)(II) (42 U.S.C. 1395w–23(c)(6)(B)(i)(II)) is amended—

(A) by striking the following new clause:

"(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

(3) Principles of Medicare Modernization.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and program information.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this Act.

(3) Principles of Medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2006, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with sufficient and appropriate support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

(g) SERVICE.—The Commission shall submit its report under subsection (d) to health care providers, health care providers, hospitals, nursing homes, suppliers of durable medical equipment, and other organizations and other private health insurance plans, and program participants, due to the implementation of the Medicare prescription drug program as part D of title XVIII of the Social Security Act.

(2) DEFINITIONS.—For purposes of this section:

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term "State pharmaceutical assistance program" means a program (other than the Medicaid program) operated by a State (and so designated with a State) that provides as of the date of the enactment of this Act assistance to low-income Medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term "program participant" means a low-income Medicare beneficiary who is a participant in a State pharmaceutical assistance program.

(i) The methodologies used for the management of costs and utilization of prescription medicines.

(ii) The prices negotiated and paid, including trends in such prices and applicable discounts and rebates with the manufacturers with prices under section 1860a–a (a)(2)(E).

(iii) The relationship of pharmacy acquisition costs to the prices so negotiated and paid.

(iv) The methodologies used to ensure access to covered outpatient prescription medicines.

(v) The impact of the program on the promotion and development of breakthrough medicines.

SEC. 106. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.—(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the "Commission") to develop a proposal for addressing such issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the Medicare prescription drug program as part D of title XVIII of the Social Security Act.

(b) COMMISSION.—The Secretary shall establish the Commission with the administrative support to carry out its responsibilities under this section.

(c) MEMBERS.—The Commission shall consist of—

(1) a Secretary of Health and Human Services (in this section referred to as the "Secretary") and such other members as the Secretary may specify.

(2) The Secretary shall designate a member to serve as chair of the Commission and the Commission shall meet at the call of the chair.

(3) The Commission shall consist of—

(a) A representative of each State that the Secretary shall identify as seeking to carry out its responsibilities under this section.

(b) A representative of each State pharmaceutical assistance program.

(c) A representative of Medicare+Choice plans.

(d) A representative of organizations and other private health insurance plans.

(e) A representative of persons who receive services from facilities of the Department of Veterans Affairs or the Department of Defense.

(f) A representative of persons who receive services from facilities of the Department of Veterans Affairs or the Department of Defense.

(4) The Commission shall meet at least once a year.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify.

(6) The Secretary may extend the time for the completion of any task under this section.

(7) The Commission shall report to Congress on the implementation of the Medicare+Choice improvements program in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and program information.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this Act.

(3) Principles of Medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2006, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with sufficient and appropriate support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

(i) The aggregate amount specified in this clause for—

(ii) 2006, is equal to $25,000,000 or

(ii) a subsequent year, is equal to the aggregate specified in this clause for the previous year increased by annual percentage increase specified in section 1855(d)(8)(B)(i) for the year involved.

(f) The Secretary shall submit to Congress a report on the application of this paragraph and may include in the report such recommendations as the Secretary deems appropriate.

(2) CONFORMING AMENDMENT.—Section 1102(h) (42 U.S.C. 1306(h)(2)) (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following:

"The previous sentence shall not apply to medicare cost-sharing relating to benefits under part D of title XVIII."

(f) E FFECTIVE DATE.—The amendments made by this section apply to premium years beginning on or after January 1, 2006, with regard to whether regulations to implement such amendments are promulgated by such date.
ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE-CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—
(1) in subparagraph (A), by striking “subparagraph (B)” and inserting “subparagraphs (B) and (E)”; and
(2) by adding at the end the following new subparagraph:
“(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare-Choice payment rate under subparagraph (A) for a year beginning with 2004, the annual per capita rate of payment for fiscal year 1997 determined under section 1876(a)(1) is adjusted to include in the rate the Secretary’s estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.”

SEC. 205. EXTENSION OF REASONABLE COST CONTRACTS.—Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395m(h)(5)) is amended to read as follows:
“(C) From 2004 to 2006, subject to clause (ii), may be extended or renewed under this subsection indefinitely.”

SEC. 206. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.—The last sentence of section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as previously amended, is amended by striking “January 31, 2004” and inserting “January 31, 2005”.

SEC. 207. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.—(a) TECHNICAL AMENDMENT CONCERNING SECRETARY’S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—In section 1862(b)(1) (42 U.S.C. 1395n(b)(1)), subsection (a)(2)(A) is amended by inserting “promptly (as determined in accordance with paragraphs (c)(3) and (d))” after “(ii)”.
reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be deemed to be on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Reconciliation Amendments of 1984 (Public Law 98–369).

(b) Clarifying Amendments to Conditional Payment Provisions.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended by—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: “An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)—

(A) by striking the first sentence and inserting the following: “A primary plan, and an entity that makes payment under a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service to which such entity has or had a responsibility to make payment with respect to such item or service. A primary plan’s responsibility with respect to an item or service may be demonstrated by a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination of liability) of payment for items or services included in a claim against the primary plan or the primary plan’s insured, or by other means.”; and

(B) in the final sentence, by striking “on the date such notice or other information is received” and inserting “on the date notice of, or information related to, a primary plan’s responsibility for such payment or other information is received”; and

(3) in subparagraph (B)(iii), as redesignated by subsection (a)(2), by striking the first sentence and inserting the following: “In order to recover payment made under this title with respect to an item or service, the United States may bring an action against any such entity. In addition, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan’s payment to any entity.”.

(c) Clerical Amendments.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended by—

(1) in paragraph (3)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking “such” before “paragraphs.”

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) In General.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

“COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

SEC. 1847. (a) Establishment of Competitive Acquisition Programs.—

(1) Implementation of Programs.—

(A) In General.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for the furnishing of goods and services described in paragraph (2) for which payment is made under this part. Such areas may differ for different items and services.

(B) phased-in implementation.—The programs shall begin—

(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs—

(1) at least 1⁄2 of such areas in 2000; and

(2) at least 1⁄2 of such areas in 2010; and

(ii) among items and services in a manner such that the programs apply to the highest cost and highest volume items and services first.

(2) Waiver of Certain Provisions.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, but such waiver shall be limited to those that do not impair the integrity and such other provisions as the Secretary determines appropriate.

(3) Items and Services Described.—The programs and services referred to in paragraph (1) are the following:

(A) Durable Medical Equipment and Medical Supplies.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and diabetic supplies, used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

(B) Other Equipment and Supplies.—Items, equipment, and supplies (as described in section 1842(s)(2)(D)) other than enteral nutritions.

(C) Off-the-Shelf Orthotics.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(a), including items used in infusion and diabetic supplies, used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

(D) Assistance for DME Products.—

(i) implementation of programs.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for the furnishing of goods and services described in paragraph (2) for which payment is made under this part. Such areas may differ for different items and services, the payment basis determined in accordance with regulations, the payment basis otherwise applied under section 1834(a).

(ii) Program Requirements.—

(A) In General.—The Secretary shall conduct the competition by considering items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under this subsection (a) with respect to such items and services.

(B) Conditions for Awarding Contract.—

(A) In General.—The Secretary may not award a contract under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(1) the entity meets quality and financial standards specified by the Secretary, and

(2) the contract is in the best interest of the United States.

(C) Waiver of Certain Provisions.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, but such waiver shall be limited to those that do not impair the integrity and such other provisions as the Secretary determines appropriate.

(4) Items and Services Described.—The programs and services referred to in paragraph (1) are the following:

(A) Durable Medical Equipment and Medical Supplies.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and diabetic supplies, used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

(B) Other Equipment and Supplies.—Items, equipment, and supplies (as described in section 1842(s)(2)(D)) other than enteral nutritions.

(C) Off-the-Shelf Orthotics.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(a), including items used in infusion and diabetic supplies, used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

(D) Assistance for DME Products.—

(i) Implementation of Programs.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for the furnishing of goods and services described in paragraph (2) for which payment is made under this part. Such areas may differ for different items and services, the payment basis determined in accordance with regulations, the payment basis otherwise applied under section 1834(a).

(ii) Program Requirements.—

(A) In General.—The Secretary shall conduct the competition by considering items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under this subsection (a) with respect to such items and services.

(B) Conditions for Awarding Contract.—

(A) In General.—The Secretary may not award a contract under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(1) the entity meets quality and financial standards specified by the Secretary, and

(2) the contract is in the best interest of the United States.

(C) Waiver of Certain Provisions.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, but such waiver shall be limited to those that do not impair the integrity and such other provisions as the Secretary determines appropriate.

(5) Physician Authorization.—The Secretary may establish a process under which a physician may prescribe a particular brand or mode of delivery of an item or service if the item or service involved is clinically more appropriate than other similar items or services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under this subsection (a) with respect to such items and services.

(6) Application.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the Secretary shall determine the competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In determining the competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items and services in the geographic area covered under the contract on a timely basis.
(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(2) PAYMENT.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on the bids submitted and accepted under this section and with respect to the items and services.

(3) PARTICIPATING CONTRACTORS.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

(A) the contractor has submitted a bid for such items and services under this section; and

(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

In this section, the term 'bid' means a request for a proposal for an item or service that includes the cost of the item or service, and where appropriate, any services that are attendant to the provision of the item or service.

(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary shall consider the similarity of the clinical efficiency and value of specific drugs, products, and services, including products that may provide a therapeutic advantage to beneficiaries, before determining that certain items and products that will be subject to bidding.

(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate agency to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries and monitoring quality of services with respect to the provision of the item or service.

(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

(1) ESTABLISHMENT.—There is established a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

(2) MEMBERSHIP; TERMS.—The Committee shall consist of 21 members as the Secretary may specify.

(3) DUTIES.—

(A) TECHNICAL ASSISTANCE.—The Committee shall provide advice and technical assistance to the Secretary with respect to the following functions:

(i) the establishment of the program under this section.

(ii) the establishment of requirements for collection of data.

(iii) the development of proposals for efficient interaction among manufacturers and distributors of the items and services and providers and beneficiaries.

(iv) THE PROVISIONS.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(B) MANAGEMENT OF THE PROGRAM.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(C) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in beneficiary out-of-pocket expenses, and quality of the items and services, and beneficiary satisfaction.

(d) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to clinical laboratory screening tests); and

(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

(3) REPORT.—The Secretary shall submit to Congress—

(A) an initial report on the project not later than December 31, 2007; and

(B) such progress and final reports on the project after such date as the Secretary determines appropriate.

(b) CONFORMITY WITH JUSTICIA. DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—

(1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1894(a) (42 U.S.C. 1395m(a)) is amended—

(A) in paragraph (1)(B), by striking "The payment basis and inserting "Subject to subparagraph (E)(i), the payment basis"; and

(B) in subparagraph (E)(ii), the payment amount otherwise recognized under such competitive acquisition program in a competitive acquisition area under section 1847(a)—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under paragraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.

(b) PAYMENT.—In the case of a drug or biological that meets the requirements for a multi-source drug under subclauses (I) and (II) of section 1860(d)(ii)(B), 105 percent of the average per unit acquisition price for any drug or biological covered under the same Medicare HCPCS code.

(c) ANNUAL REPORTS.—The Secretary shall perform such additional functions to assist the Secretary in carrying out this section, the term 'average acquisition price' means, with respect to a drug or biological and with respect to each dosage form and each strength of the drug or biological product (without regard to any special packaging, labeling, or identifying on the dosage form or

SEC. 303. REFORM OF PAYMENT FOR DRUGS AND BIOLOGICALS UNDER THE MEDICARE PROGRAM.

(a) PAYMENT REFORM.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended to read as follows:

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—

(1) GENERAL RULE.—If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological shall be based on the following:

(A) MULTIPLE SOURCES (GENERIC) DRUGS.—In the case of a drug or biological that meets the requirements for a multi-source drug under subclauses (I) and (II) of section 1860(d)(ii)(B), 105 percent of the average unit acquisition price for any drug or biological covered under the same Medicare HCPCS code.

(B) SINGLE SOURCE (BRAND) DRUGS AND BIOLOGICALS.—In the case of a drug or biological that meets the requirements for a single source drug under section 1871(a)(7)(A)(iv), 105 percent of the average acquisition price for the drug or biological.

(c) ACCESS EXCEPTION.—The Secretary may modify the rate otherwise applicable in order to assure access to necessary drugs and biologicals in the case of sole community providers in rural and other areas where the providers are not reasonably able to obtain the drugs and biologicals at the payment rates otherwise applicable. Such modification shall not result in a change of more than 15 percent of the rate otherwise applicable.

(d) DATA-RELATED EXCEPTION.—If the Secretary determines that there is insufficient data available with respect to the average acquisition price for a quarter or that, because of a significant change in price from quarter-to-quarter, the available data on the average acquisition price does not reflect the actual, current acquisition cost for the drug or biological, the Secretary may substitute for the quarters involved an appropriate average price for the drug or biological for such average acquisition price.

(e) APPLICATION OF NDC CODES.—If the Secretary determines that it is appropriate to use national drug code (NDC) instead of HCPCS codes, in applying subparagraph (A) the reference to the same HCPCS code shall mean a reference to the appropriate national drug code for those drugs or biologicals that are therapeutically and pharmaceutically equivalent and bioequivalent for purposes of section 1871(a)(7)(A).

(f) DEFINITION OF AVERAGE ACQUISITION PRICE.—

(1) IN GENERAL.—For purposes of this section, the term 'average acquisition price' means, with respect to a drug or biological and with respect to each dosage form and each strength of the drug or biological product (without regard to any special packaging, labeling, or identifying on the dosage form or

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product or package), the average of all final sales prices charged by the manufacturer of the drug or biological product in the United States, excluding sales exempt from inclusion in the average based on the lowest prices charged by the manufacturer of the drug or biological product in the United States. The average price shall be calculated net of all of the following (as estimated by the Secretary):

1. (A) price discounts and rebates on sales of such drug or biological product.
2. (B) NDC (national drug code).
3. (C) Federal, state, and local government purchases.
4. (D) Charge-backs.
5. (E) Price concessions.
6. (F) Public sector purchases.
7. (G) Returns.
8. (H) speilage and other factors.

(3) FEE ALLOWANCE.—For purposes of this section, the term "fee allowance" means a discount or other reduction in price allowed by the manufacturer to a buyer, in the form of a cash payment or value given in return for the purchase or use of a drug or biological product, excluding rebates.

(4) FORM OF REPORTING.—Information required to be reported under subparagraph (A) shall be reported in a form and manner specified by the Secretary. The information required to be reported shall include the identification of the generic name of the drug (or biological product), the manufacturer's name, the average price charged, the total number of units of such sales, and the number of patients in each price tier.

(5) PRICE REPORTING REQUIREMENT.—

(A) IN GENERAL.—As a condition for payment of any drug or biological product, a manufacturer shall under this subsection, the manufacturer of the drug or biological shall—

(i) report, on a quarterly basis, to the Secretary information so reported or required to be reported under this subsection.

(B) APPLICATION OF ENFORCEMENT PROVISIONS.—The provisions of subsection (b)(2) shall apply to charges for such drugs or biologicals under this part, the Secretary shall pay the amounts attributable to applicable deductible and coinsurance amounts to the pharmacy. Such a dispensing fee shall be subject to adjustment from year to year based on changes in the consumer price index over time and may be adjusted as the Secretary determines to be appropriate to reflect differences in the costs of dispensing different drugs.

(6) MULIPLE PUSHES.—In establishing the payment amounts under this subsection, the Secretary shall establish the payment amount for intravenous chemotherapy administration by push technique based on the administration of a single drug. The Secretary shall apply a uniform reimbursement rate under subsection (A) in general.

(7) PAYMENT REQUIRED ON AN ASSIGNMENT-RELATED BASIS.—

(A) IN GENERAL.—Payment for any drug or biological product for which payment may be made under this part may be made only on an assignment-related basis.

(B) APPLICATION OF ENFORCEMENT PROVISIONS.—The provisions of subsection (b)(2) shall apply to charges for such drugs or biologicals in the same manner as they apply to charges for such drugs or biologicals in subsection (c).
(d) **CANCER THERAPY MANAGEMENT SERVICES.**—Beginning in 2005, the Secretary shall recognize and establish a payment amount for the service of cancer therapy management to account for the greater pre-service and post-service requirements associated with interventions and consultations conducted by physicians treating cancer patients compared to typical visits and consultations. The payment amount shall reflect the level and type of the related visit or consultation.

(e) **OTHER SERVICES WITHOUT PHYSICIAN WORK RELATIVE VALUE UNITS.**—Beginning in 2005, the Secretary shall develop a revised methodology for determining the payment amounts for services that are paid under the fee schedule by section 1848 of the Social Security Act (42 U.S.C. 1395w-4) and that do not have physician work relative value units, including radiation oncology services. Such methodology shall result in payment amounts that fully cover the costs of furnishing such services. Until such time as the methodology for such services is revised and implemented, all such services shall be protected from further payment cuts due to factors such as shifts in utilization or removal or specialty's services that are paid under the fee schedule established by section 1848 and that do not have physician work relative value units.

(f) **IMPROVEMENTS.**—Not later than April 1, 2004, the Secretary shall submit to Congress a report on the payment amounts that are to be adopted under subsections (b), (c), (d), and (e) of this section.

(g) **INSTITUTE OF MEDICINE STUDY.**

(1) **GENERAL.**—The Secretary shall request the Institute of Medicine to conduct the study described in this subsection.

(2) **BASELINE STUDY.**—The first phase of the study shall include the following objectives:

(A) an assessment of the extent to which the current Medicare payment system, prior to implementation of the amendments made by this section, facilitates appropriate access to care for cancer patients in the various treatment settings;

(B) the identification of the comprehensive range of services needed and the specific support services that are essential to be furnished to Medicare patients with cancer;

(C) a discussion of the practice standards necessary to assure the safe provision of services to cancer patients; and

(D) an analysis of the extent to which the current Medicare payment system supports the role of nurses in the provision of oncology services and recommendations for any necessary improvements in the payment system in that regard.

(E) The development of a framework for assessing how the amendments made by this Act affect the provision of care to Medicare patients with cancer.

(F) **CONSULTATION.**—The Institute of Medicine shall conduct the study in consultation with:

(A) the Secretary of Health and Human Services; and

(B) representatives of the following:

(i) the American Cancer Society;

(ii) the American Society of Clinical Oncology;

(iii) the American Psychosocial Oncology Society; and

(iv) national voluntary cancer organizations and other healthcare professionals who treat cancer patients in planning and carrying out this study.

(G) The study required by paragraph (2) shall be submitted to the Congress and the Secretary of Health and Human Services no later than June 30, 2004.

(H) The study required by paragraph (3) shall be submitted to the Congress and the Secretary of Health and Human Services no later than December 31, 2004.

(i) **STUDY OF PAYMENTS FOR BLOOD CLOTTING FACTORS AND OTHER BIOLOGICALS.**—In general, the Secretary of Health and Human Services shall provide for a study of the appropriateness of the Medicare payment methodology for blood clotting factors and other biologicals under part B of title XVIII of the Social Security Act. Not later than 9 months after the date of the enactment of this Act, the Secretary shall submit a report to the Congress and shall include in such report recommendations regarding whether to apply the payment methodology provided under the amendment made by subsection (a)(1) and alternative recommendations for appropriate dispensing fees.

(ii) **DELAY IN EFFECTIVE DATE.**—The amendment made by subsection (a)(1) shall not apply to blood clotting factors furnished before the first day of the first calendar year that begins at least 6 months after the date the report required by paragraph (1) has been submitted to the Congress.

**SECTION 304. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.**

(a) **IN GENERAL.**—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the "project") to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the Medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act. Under the project:

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of the demonstration project in identifying underpayments and overpayments and recouping overpayments under the Medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act.

(b) **SCOPE AND DURATION.**

(1) **SCOPE.**—The project shall cover at least 2 States that are among the States with:

(A) the highest per capita utilization rates of Medicare and Medicaid services; and

(B) at least 3 contractors.

(2) **DURATION.**—The project shall last for not longer than 3 years.

(c) **WAIVER.**—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) **QUALIFICATIONS OF CONTRACTORS.**

(1) **IN GENERAL.**—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) **INELIGIBILITY FOR CERTAIN CONTRACTORS.**—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity has a determination under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395w-4), or a Medicare Administrative Contractor under section 1874 of such Act.

(3) **PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY WITH PRIVATE INSURER CONTRACTS.**—If the Secretary determines that the entity has demonstrated proficiency with contracts to recovery audit contractors under this section, the Secretary shall give preference to such an entity.

(iii) The Secretary determines that the entity has demonstrated proficiency with contracts to recovery audit contractors under this section.

(iv) **CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.**—A recovery of an overpayment to a provider by a recovery audit contractor shall not be used to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) **REPORT.**—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the Medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

**TITLE IV—RURAL HEALTH CARE IMPROVEMENTS**

**SECTION 401. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARING HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS.**

(a) **EQUALIZING DSH PAYMENT AMOUNTS.**

(1) **IN GENERAL.**—Section 1886(d)(5)(F)(v) (42 U.S.C. 1395ww(d)(5)(F)(v)) is amended by inserting "and, after October 1, 2004, for any other period described in clause (iv), after clause (iv)(I),", in the matter preceding subclause (I).

(2) **CONFORMING AMENDMENTS.**—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in clause (iv)—

(i) in subclause (I), by inserting "and before October 1, 2004, after "April 1, 2001,"; and"

(ii) after clause (iv), by inserting "or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii) after clause (xiii);"

(B) in subclause (III), by inserting "and before October 1, 2004, after "April 1, 2001,"; and"

(C) in subclause (IV), by inserting "and before October 1, 2004, after "April 1, 2001," and"

(D) in subclause (V), by inserting "or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii) after clause (xii);"

(3) **EQUALIZING DSH PAYMENT AMOUNTS FOR RURAL HOSPITALS.**

(a) **CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.**—A recovery of an overpayment to a provider by a recovery audit contractor shall not be used to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) **REPORT.**—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the Medicare program and recommendations on the cost-effectiveness of extending or expanding the project.
(B) in clause (viii), by striking "The formula" and inserting "For discharges occurring before October 1, 2004, the formula"; and
(C) in each of clauses (x), (xi), (xii), and (xiii), by striking "15 percent of the reasonable costs for such services" and inserting "15 percent of the reasonable costs for such services other than covered discharges occurring before October 1, 2004, for purposes".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after October 1, 2004.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended—

(i) by inserting "and ending on or before September 30, 2003," after "October 1, 1995," and;

(ii) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clause:

"(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.".

(b) CONFORMING AMENDMENTS.—

(1) INCREASE IN PAYMENT AMOUNTS.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking "in fiscal year 1997," before "a regional adjusted DRG prospective payment rate";

(B) in the matter preceding clause (i), by striking "15 percent of the reasonable costs for such services", and inserting "a regional adjusted DRG prospective payment rate";

(C) in clause (i), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and

(D) in clause (ii), by striking "and" after the semicolon at the end.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharges occurring on or after October 1, 2004.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to cost reporting periods beginning on or after October 1, 2004.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1833(t)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 1395l(t)(3)) are each amended by inserting "With respect to discharges occurring before October 1, 2004, for purposes of section 1886.".

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency and methodology for making updates under section 1395m(g)(1) (42 U.S.C. 1395m(g)(1))

(c) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2005.

SEC. 405. IMPROVEMENT TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENTS.—

(1) IN GENERAL.—Sections 1886(e)(1)(A), 1886(g), and 1833(t)(3) (42 U.S.C. 1395f(e)(1); 1395m(g); 1395l(t)(3)) are amended by striking "equal to 102 percent of the reasonable costs for such services, not to exceed the national average weighted market basket to reflect the most current data available, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency and methodology for making updates under section 1395m(g)(1), including an explanation of the reasons for, and options considered, in determining such frequency.

(c) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2005.

SEC. 406. COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.

(a) IN GENERAL.—

(1) IN GENERAL.—Section 1807(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting "CERTAIN" before "EMERGENCY"

(ii) by striking "PHYSICIANS" and inserting "PROVIDERS";

(B) by striking "emergency room physicians who are on-call (as defined by the Secretary) to provide emergency services" and inserting "emergency room physicians who are on-call (as defined by the Secretary) to provide emergency services"; and

(C) by striking "physicians’ services" and inserting "services covered under this title".

(b) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.

SEC. 407. ALLOCATE SWING BEDS AND ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL LIMIT OF 25 BEDS.
Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new subparagraph:

(4) FUNDING.—

(a) In general.—Subject to subparagraph (B), payment for grants made under this subparagraph for fiscal years beginning after October 1, 2004, shall be made by the Secretary, consistent with clause (iv), to hospitals in rural areas (as defined in section 1886(h)(1)(B) of the Social Security Act) and in urban areas (as defined in section 1886(h)(1)(B) of the Social Security Act) that meet the applicable criteria established under this section.

(b) Calculation.—The Secretary shall make payments under this subparagraph in an amount that exceeds the sum of the otherwise applicable resident limit for a fiscal year by an amount equal to 50 percent of the difference between the otherwise applicable resident limit for a fiscal year and the applicable resident limit for a fiscal year.

(c) Allocation.—The Secretary shall allocate payments under this subparagraph to hospitals in rural areas and urban areas on a pro rata basis.

(d) Payment for demonstration projects.—The Secretary shall make payments under this subparagraph in an amount that exceeds the sum of the otherwise applicable resident limit for a fiscal year by an amount equal to 50 percent of the difference between the otherwise applicable resident limit for a fiscal year and the applicable resident limit for a fiscal year.

(5) ANNUAL ADJUSTMENT LIMITATION.—In no case may the amount of payment made under this subparagraph for a fiscal year exceed $25,000,000.

(6) CONFORMING AMENDMENT.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by striking subsection (j).

SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) In general.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in subparagraph (f)(1), by inserting ‘‘subject to subparagraph (i)’’, after ‘‘October 1, 1997’’;

(2) in subparagraph (h)(i), by inserting ‘‘subject to subparagraph (i)’’, after ‘‘subparagraphs (f) and (g)’’;

(3) by adding at the end the following new subparagraph:

(‘‘i’’) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(i) REDUCTION IN LIMIT BASED ON UNUSED RESIDENT POSITIONS.—

(1) IN GENERAL.—If a hospital’s resident level (as defined in clause (iii)(i)) is less than the otherwise applicable resident limit (as defined in clause (iii)(ii)) for each of the reference periods (as defined in clause (iii)(iii)) during the reference period, the applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in clause (iii) (or clause (iv) if applicable).

(ii) PERIODS DEFINED.—In this clause, the term ‘‘reference periods’’ means, with respect to a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not submitted) on or before September 30, 2002.

(iii) REFERENCE RESIDENT LEVEL.—Subject to clause (iv), the reference resident level specified in this clause for a hospital during each reference period shall be—

(A) the highest resident level for the hospital during any of the reference periods (as defined in clause (ii));

(B) the number of beds used at any time for acute care inpatient services (as determined on an annual, average basis, 96 hours per patient); and

(C) the number of beds used at any time for acute care inpatient services during any of the reference periods (as defined in clause (ii)), consistent with clause (iv).

(iv) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital that is the resident level for the hospital for the cost reporting period that includes July 1, 2003.

(v) AFFILIATION.—With respect to hospitals with a merger or affiliation of the same affiliated group (as defined by the Secretary under subparagraph (H)(ii)), the provisions of this section shall be applied with respect to such an affiliation by deeming the affiliated group to be a single hospital.

(vi) REDISTRIBUTION.—

(A) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in the resident level for a hospital during each reference period.

(B) EFFECTIVE DATE.—No increase under subparagraph (A) may be taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2003, or before the date of the hospital’s application for a new resident position under this clause.

(C) REPORT ON EXTENSION OF APPLICATIONS UNDER DISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident positions under this section.

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARLEM LENS PROGRAM FOR MEDICAL RURAL HOSPITALS AND SOLEMN COMMUNITY HOSPITALS UNDER PROSECUTIVE AND DUAL-HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARLEM LENS PROVISIONS.—

(1) IN GENERAL.—Section 1833(t)(7)(D)(I) (42 U.S.C. 1395t(7)(D)(I)) is amended—

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to payments made on or after October 1, 2004.

(3) REIMSTATEMENT OF PERIODIC INTERIM PAYMENT.—

(1) IN GENERAL.—Section 1834(e)(2) (42 U.S.C. 1395f(e)(2)) is amended—

(A) in the matter before subparagraph (A), by inserting ‘‘, in the cases described in subparagraphs (A) through (D) after ‘‘1996’’;

(B) by striking ‘‘and’’ at the end of subparagraph (C);

(C) by adding ‘‘and’’ at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

‘‘(E) inpatient critical access hospital services.’’

(2) DEVELOPMENT OF ALTERNATIVE METHODS OF PERIODIC INTERIM PAYMENTS.—With respect to inpatient critical access hospital services, the Secretary may develop alternative methods for such payments that are based on expenditures of the hospital.

(3) REIMSTATEMENT OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after January 1, 2004.

(4) CONFORMING AMENDMENT.—Section 1834(e)(2)(E) of the Social Security Act, as added by paragraph (1), shall be amended—

(A) by striking the comma at the end of subparagraph (E); and

(B) by adding ‘‘and’’ at the end of subparagraph (F).

(5) FUNDING.—

(a) IN GENERAL.—Section 1834(e)(2)(F) is amended—

(1) in subparagraph (H)(i), by inserting ‘‘subject to subparagraph (I)’’, after ‘‘for the fiscal year ending June 30, 2002’’;

(2) in subparagraph (H)(ii), by adding ‘‘and’’ at the end of subparagraph (H); and

(3) by adding at the end the following new subparagraph:

‘‘(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(i) REDUCTION IN LIMIT BASED ON UNUSED RESIDENT POSITIONS.—

(1) IN GENERAL.—If a hospital’s resident level (as defined in clause (iii)(i)) is less than the otherwise applicable resident limit (as defined in clause (iii)(ii)) for the reference periods (as defined in clause (iii)(iii)) during a reference period, the applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in clause (iii) (or clause (iv) if applicable).

(ii) PERIODS DEFINED.—In this clause, the term ‘‘reference periods’’ means, with respect to a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled or, if not submitted, on or before September 30, 2002.

(iii) REFERENCE RESIDENT LEVEL.—Subject to clause (iv), the reference resident level specified in this clause for a hospital during each reference period shall be—

(A) the highest resident level for the hospital during any of the reference periods (as defined in clause (iii));

(B) the number of beds used at any time for acute care inpatient services (as determined on an annual, average basis, 96 hours per patient); and

(C) the number of beds used at any time for acute care inpatient services during any of the reference periods (as defined in clause (iii)), consistent with clause (iv).
(A) in the heading, by striking "small" and inserting "certain";

(B) by inserting "or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in an area with fewer than 100 beds"; and

(C) by striking "2004" and inserting "2006".

(2) EFFECTIVE DATE.—The amendment made by subsection (a)(2) shall apply with respect to payments for OPD services furnished on or after January 1, 2004.

(3) STUDY; ADJUSTMENT.—

(1) STUDY.—The Secretary shall conduct a study to determine if, under the prospective payment system for hospital outpatient department services under section 1833(e) of the Social Security Act (42 U.S.C. 1395l(t)), costs incurred by rural providers of services by ambulatory payment classification groups (APCs) exceed those costs incurred by urban providers of services.

(2) Adjustment.—Insofar as the Secretary determines under paragraph (1) that costs incurred by rural providers exceed those costs incurred by urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(e) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) In General.—Section 1886(h)(2)(A) (42 U.S.C. 1395w(h)(2)(A)) is amended—

(1) in clause (ii), by striking "or (iii)" and inserting "clauses (ii), (iii), and (iv)"; and

(2) by adding at the end the following new clause:

"(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

"(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

"(II) Federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were not furnished by an individual affiliated with a rural health clinic or a Federally qualified health center.

"(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to payments for services furnished on or after January 1, 2004.

SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) In General.—Section 1861(dd)(3)(B) (42 U.S.C. 1395l(dd)(3)(B)) is amended by inserting "or nurse practitioner (as defined in subsection (aa))" after "the physician (as defined in subsection (i))".

(b) PROHIBITION ON NURSE PRACTITIONER CERTIFICATION NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395a(7)(A)(i)(I)) is amended by inserting "(which for purposes of this subparagraph does not include a nurse practitioner or attending physician (as defined in section 1861(dd)(3)(B)))".

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(i) (42 U.S.C. 1395l(i)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–468), as paragraph (9); and

(2) by adding at the end the following new paragraph:

"(10) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW MEDICARE POPULATION QUARTILES.—(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for an increase in the base rate of the payment for such services, as estimated to be in effect for any cost reporting period beginning on or after January 1, 2004, for which such services were furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during the applicable base cost reporting period is in the lowest three quartiles of all rural county populations.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of Medicare beneficiaries residing in the area that is in the lowest three quartiles of all rural county populations.

SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) In General.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during the applicable base cost reporting period is in the lowest three quartiles of all rural county populations.

"(ii) The report shall include receivables and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

"(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

INTERIM FINAL RULE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1) that will be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period not more than 60 days), for public comment, as is consistent with this subsection.

SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIAN SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule resulting from the geographic cost of practice index and variation in such increases by State and physician specialty and area of practice.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).
(a) In general.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(i) WAGE LEVELS.—The Secretary and inserting "WAGE LEVELS.—"

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

(i) Except as provided in subclause (ii), for discharges occurring or on or after October 1, 2003, the Secretary shall substitute the '02 percent' for the proportion determined under subparagraph (A)(i), to number of Medicare beneficiaries determined under subparagraph (B).

(ii) HOLD HARMLESS FOR CERTAIN HOSPITALS.—If the application of subclause (i) would result in lower payments to a hospital than would otherwise be made, then this subparagraph shall be applied as if this clause had not been enacted.

(b) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: The Secretary shall apply the provisions of this paragraph for any period as if the amendments made by section 402(a) of the Medicare Prescription Drug and Modernization Act of 2003 had not been enacted.

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

(i) Except as provided in subparagraph (A)(i), the ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(ii)), to number of Medicare beneficiaries determined under subparagraph (B).

(ii) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that would otherwise be made for such services furnished or after January 1, 2004, made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of Medicare beneficiaries determined under subparagraph (B), an aggregate total of 20 percent of the total of the Medicare beneficiaries determined under such paragraph.

(C) DETERMINATION OF RATIOS.—

(1) IN GENERAL.—In the case of physicians' services furnished or after January 1, 2004, the Secretary shall include, as part of the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county for purposes of this subsection.

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395m(m)) is amended—

(A) by inserting "(1)" after "(m)"; and

(B) by adding at the end the following new paragraphs:

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(iii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(i)), to number of Medicare beneficiaries determined under subparagraph (B).

(iv) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that would otherwise be made for such services furnished or after January 1, 2004, made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of Medicare beneficiaries determined under subparagraph (B), an aggregate total of 20 percent of the total of the Medicare beneficiaries determined under such paragraph; and

(C) DETERMINATION OF RATIOS.—

(1) IN GENERAL.—In the case of physicians' services furnished or after January 1, 2004, the Secretary shall include, as part of the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county for purposes of this subsection.

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(v) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(i)), to number of Medicare beneficiaries determined under subparagraph (B).

(vi) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that would otherwise be made for such services furnished or after January 1, 2004, made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of Medicare beneficiaries determined under subparagraph (B), an aggregate total of 20 percent of the total of the Medicare beneficiaries determined under such paragraph.

(C) DETERMINATION OF RATIOS.—

(1) IN GENERAL.—In the case of physicians' services furnished or after January 1, 2004, the Secretary shall include, as part of the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county for purposes of this subsection.

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(vii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(i)), to number of Medicare beneficiaries determined under subparagraph (B).

(viii) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that would otherwise be made for such services furnished or after January 1, 2004, made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of Medicare beneficiaries determined under subparagraph (B), an aggregate total of 20 percent of the total of the Medicare beneficiaries determined under such paragraph.

(C) DETERMINATION OF RATIOS.—

(1) IN GENERAL.—In the case of physicians' services furnished or after January 1, 2004, the Secretary shall include, as part of the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county for purposes of this subsection.

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(v) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that would otherwise be made for such services furnished or after January 1, 2004, made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of Medicare beneficiaries determined under subparagraph (B), an aggregate total of 20 percent of the total of the Medicare beneficiaries determined under such paragraph.

(C) DETERMINATION OF RATIOS.—

(1) IN GENERAL.—In the case of physicians' services furnished or after January 1, 2004, the Secretary shall include, as part of the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county for purposes of this subsection.
(1) PAYMENT BASED ON REASONABLE COSTS.—The amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

(2) PAYMENT FOR NON-AMBULATORY SERVICES.—Notwithstanding section 432, no insurance, deductible, or other cost-sharing otherwise applicable under such part B shall apply with respect to such test.

SEC. 420. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC ADJUSTMENTS OF PAYMENTS FOR PHYSICIANS' SERVICES.

Section 1848(e)(3)(B) (42 U.S.C. 1395ww(d)(4)(e)(3)) is amended—

(1) by striking "subparagraphs (B) and (C)" and inserting "subparagraph (B)"; and

(2) by adding at the end the following new subparagraphs:

(E) FLOOR FOR WORK GEOGRAPHIC INDICES.—

''(i) In general.—For purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2008, after calculating the work geographic indices in subparagraph (A), the Secretary shall increase any such index by one.

''(ii) Work floor index.—For purposes of subparagraph (A), the term 'work floor index' means—

''(I) 0.980 with respect to services furnished during 2004; and


(F) FLOOR FOR PRACTICE EXPENSE AND MALPRACTICE GEOGRAPHIC INDICES.—For purposes of payment for services furnished on or after January 1, 2000, and before January 1, 2008, after calculating the practice expense index and malpractice indices in instances (i) and (ii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index by one to 1.00 for any locality for which such index is less than 1.00.

SEC. 421. AMBULANCE PAYMENT RATES.

(a) PAYMENT RATES.—Section 1884(i)(3)(B) (42 U.S.C. 1395m(i)(3)) is amended to read as follows:

''(3) Payment rates.—

''(A) In general.—Subject to any adjustment under subparagraph (B) and paragraph (9) and the full payment of a national mileage rate pursuant to subparagraph (2)(E), in establishing such fee schedule, the following rules shall apply:

''(i) Payment rates in 2003—

''(I) Ground ambulance services furnished under this part in 2003, the Secretary shall set the payment rates under the fee schedule for such services at a rate based on the average costs as determined by the Secretary on the basis of the most recent and reliable information available incurred by full cost ambulance suppliers in providing non-emergency ambulance services, support, ambulance services covered under this title, with adjustments to the rates for other ground ambulance service levels to be determined based on the rule established under paragraph (1). For the purposes of the preceding sentence, the term 'full cost ambulance supplier' means a supplier for whom volunteers or other unpaid staff comprise less than 20 percent of the supplier's total staff and which receives less than 20 percent of space and other capital assets free of charge.

''(II) Air ambulance services.—In the case of ambulance services not described in subparagraph (I) that are furnished under this part in 2003, the Secretary shall set the payment rates under the fee schedule for such services based on the rule established under paragraph (1),

''(II) Payment rates in subsequent years for all ambulance services.—In the case of any ambulance service furnished under this part in 2004 or any subsequent year, the Secretary shall set the payment rates under the fee schedule for such service at amounts equal to the payment rate under the fee schedule for that service furnished during the previous year plus the percent increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

''(B) Adjustment in rural rates.—For years beginning with 2004, the Secretary, after taking into consideration the recognition provided by the report submitted under section 221(b)(3) the Medicare, Medicaid, and SCHIP Benefits Improvements and Protection Act of 2000, shall adjust the fee schedule to 1.00 rates that would otherwise apply under this subsection for ambulance services provided in low density rural areas based on the increased cost (if any) of providing such services in such areas.

(b) CONFORMING AMENDMENT.—Section 221(c) of BIPA is repealed.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. ADJUSTMENT FOR INDIRECT COSTS OF MEDICAL EDUCATION (IME).


(1) by striking ''(vi)'' after ''(vi)''; and

(2) by adding at the end the following new clause:

''(vii) On or after October 1, 2005, 'c' is equal to 1.35.''

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGY UNDER INPATIENT HOSPITAL PSA R TPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(1) by striking ''and'' at the end of subparagraph (A); and

(2) by adding at the end the following new subparagraph:

''(VII) The Secretary shall by regulation periodically update a list of all the services and technologies for which an application for coverage under Medicaid was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which prior review has been performed under section 1862(b)(5) of such Act. Nothing in this subsection shall be construed as affecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1)(B '').

(b) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following new clause:

''(VIII) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vii)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

''(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for coverage under Medicaid was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which prior review has been performed under section 1862(b)(5) of such Act. Nothing in this subsection shall be construed as affecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1)(B ').'

''(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

''(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, managed care organizations, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Medicare Appeals Council before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

''(IV) The Secretary shall specify in the notice of proposed rulemaking whether the service or technology represents a substantial improvement.

''(V) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, managed care organizations, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Medicare Appeals Council before publication of a proposed rulemaking regarding whether service or technology represents a substantial improvement.

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—


''(I) by inserting ''(I)'' after ''(vi)''; and

''(II) by adding at the end the following new subparagraph:

''(vii) (II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD-9-CM (or a successor coding methodology) that enables the identification of specific discharges in which the service or technology has been used.''

''(2) Adjustments on threshold.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is further amended by adding at the end the following new clause:

''(IX) on or after October 1, 2005, 'c' is equal to 1.35.''

(b) CONFORMING AMENDMENT.—Section 221(c) of BIPA is repealed.
a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, the new technology would no longer qualify for classification, but in such case, the Secretary shall make a determination with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(b) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1395ww(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(iii)) is amended by inserting after "the estimated average cost" so that they apply to classification for such services or technology the following: "(baselined by rate applied to costs under subparagraph (A))", such clause shall not affect the application of paragraph (4)(C)(iii).

(2) EFFECTIVE DATE.—(I) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2004. In the case of an application for a classification of a technology under section 1886(d)(6)(B), the applicable Federal percentage is 75 percent and the applicable Puerto Rico percentage is 41 percent and the applicable percentage is 75 percent.

SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM.

(a) IN GENERAL.—Section 1395ww(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) is amended by adding a sentence at the end of the section, as follows:

"(A) In order to recognize commuting patterns among Metropolitan Statistical Areas and small areas and rural areas, the Secretary shall establish a process, upon application of a subsection (d) hospital that establishes that it is a qualifying hospital described in subparagraph (B), for an increase of the wage index applied under paragraph (3)(E) for the hospital in the amount computed under subparagraph (D).

"(B) A qualifying hospital described in this subparagraph is a subsection (d) hospital—

"(i) which has at least 10 percent of its employees who reside in one or more higher wage index areas;

"(ii) for which the number of employees of the hospital that reside in one or more higher wage index areas is greater than 75 percent of the total number of employees of the hospital, and

"(iii) the average wages of which exceed the average wages of the area in which the hospital is located;

"(iv) during fiscal year 2004, the applicable Federal percentage is 75 percent and the applicable Puerto Rico percentage is 41 percent and the applicable percentage is 75 percent.

(b) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to wage index areas in which hospitals are operating on or after January 1, 2004.

(c) APPLICA TION OF EXCEPTION FOR HOSPITALS IN THE DISTRICT OF COLUMBIA.—Subsection (c) of section 1395ww(d) is amended—

"(1) by striking "and" at the end of subparagraph (A); and

"(2) by adding at the end the following new subparagraph:

"(E) §1395ww(d) is amended—

"(1) by striking "and" at the end of paragraph (f).

"(2) by adding a new paragraph (g) at the end of the section, as follows:

"(G) A hospital that is reclassified under subparagraph (E) shall be eligible for a new technology adjustment in the case mix under paragraph (3) if the average wages in the area in which the hospital is located is greater than 75 percent of the average wages in the area in which the hospital resides in any higher wage index area.

SEC. 505. CLARIFICATIONS TO CERTAIN EXEMPTIONS.

(a) ADMISSION TO HOSPITALS IN PUERTO RICO.—Section 1877(h)(7)(B)(ii) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended—

"(i) in clause (i), by striking "and" at the end of subparagraph (A), and

"(ii) by striking "is inconsistent with the purpose of permitting" and inserting "for purposes of permitting permitting".

(b) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to hospitals in Puerto Rico on and after January 1, 2004.

(c) APPLICA TION OF EXCEPTI ON FOR HOSPITALS UNDER DEVELOPMENT.—Section 1395ww(d) is amended by striking subparagraph (E) and inserting the following:

"(E) A hospital that establishes that it is a qualifying hospital described in paragraph (D) for a period is not eligible for reimbursement for Medicare services furnished on or after October 1, 2003.

SEC. 506. IMPROVEMENT OF PAYMENT FOR NEW TECHNOLOGY.—Section 1395ww(d)(5)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(D)) is amended—

"(i) by striking "(ii) after October 1, 2003," and inserting "(ii) after the effective date of this subsection," and

"(ii) by adding at the end the following new subparagraph:

"(K) The Secretary shall, in determining whether a hospital is under development as of such date, consider—

"(1) whether plans have been completed, such plans as have been completed have been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received; and

"(2) any other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

Title II—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO BILLS FOR RESIDENTS.—Section 1877(h)(7)(B)(i)(II) of the Social Security Act (42 U.S.C. 1395ww(d)(7)(B)(i)(II)) is amended by striking subparagraph (A) and inserting the following:

"(A) A hospital that is reclassified under subparagraph (B) shall be increased by 128 percent.

(b) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to skilled nursing facilities on or after January 1, 2004.

(c) APPLICA TION OF EXCEPTI ON FOR HOSPITALS UNDER DEVELOPMENT.—Section 1395ww(d) is amended—

"(i) by striking "and" at the end of paragraph (f), and

"(ii) by adding a new paragraph (g) at the end of the section, as follows:

"(G) A hospital that is reclassified under subparagraph (E) shall be eligible for a new technology adjustment in the case mix under paragraph (3) if the average wages in the area in which the hospital resides in any higher wage index area is greater than 75 percent of the average wages in the area in which the hospital is located.

(d) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to hospitals on or after January 1, 2004.

SEC. 512. CLAIMS TO CERTAIN MEDICARE LIMITS ON PHYSICIAN REFERRALS.

(a) OWNERSHIP AND INVESTMENT INTERESTS IN WHOLE HOSPITALS.—

"(1) IN GENERAL.—Section 1877(h)(7) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

"(A) by striking subparagraph (A) at the end of subsection (B); and

"(B) by redesignating subparagraph (B) as subparagraph (C) and inserting after subparagraph (B) the following:

"(C) The hospital is not a specialty hospital (as defined in subsection (d)(7)); and

"(2) DEFINITION.—Section 1395ww(h)(7) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

"(i) by striking "and" at the end of the paragraph; and

"(ii) by striking "subject to paragraph (4)(C)(iii),".

(b) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to referrals made for designated health services on or after January 1, 2004.
(2) by striking the period at the end of paragraph (4) and inserting ‘‘; and’’; and
(3) by inserting after paragraph (4) the following new paragraph:

‘‘(5) An examination of the degree to which new technology, including coverage determination of the Centers for Medicare & Medicaid Services, has affected the volume of physicians’ services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians’ offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

Subtitle II—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395w–4(s)(2)) is amended—

(1) in subparagraph (U), by striking ‘‘and’’ at the end;

(2) in subparagraph (V), by inserting ‘‘and’’ at the end; and

(3) by adding at the end the following new subparagraph:

‘‘(W) an initial preventive physical examination (‘‘ww’’) The term ‘initial preventive physical examination’ means physicians’ services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services (excluding clinical laboratory tests), as determined by the Secretary, consistent with the recommendations of the United States Preventive Services Task Force.’’.

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395f–2(b)) is amended—

(A) by striking ‘‘and’’ at the end of subparagraph (6), and

(B) by inserting, before ‘‘(6),’’ the following: ‘‘; and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)).’’.

(2) COINSURANCE.—Section 1833(a) (42 U.S.C. 1395f–2(a)) is amended—

(A) in clause (N), by inserting ‘‘(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))’’ after ‘‘80 percent’’; and

(B) in clause (O), by inserting ‘‘(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))’’ after ‘‘80 percent’’.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the results of the study conducted under paragraph (1).

SEC. 602. STUDIES ON ACCESS TO PHYSICIANS’ SERVICES.

(a) GAO STUDY OF BENEFICIARY ACCESS TO PHYSICIANS’ SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians’ services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians’ services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians’ services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR PHYSICIAN SERVICES.—

(1) STUDY.—The Medicare Payment Advisory Commission shall submit to Congress a report on the practice expense component of payments for physicians’ services, after the transition to a full resource-based payment system in 2002, under section 1848(f) of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(A) the effect of such refinements on payment for physicians’ services.

(B) The interaction of the practice expense component with other components of and adjustments to Medicare’s payment for physicians’ services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians’ services.

(5) The effect of such refinements on physician participation under the medicare program.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians’ services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(A) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act).

(B) An examination of the relative growth of volume in physician services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determination of the Centers for Medicare & Medicaid Services, has affected the volume of physicians’ services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians’ offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.
SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING Tests.

(a) CHOLESTEROL AND OTHER BLOOD LIPID SCREENING.

(1) in subparagraph (I) of section 1832(b)(2)(B) (42 U.S.C. 1395x((2)), as amended by section 611(a), is amended—

(2) in paragraph (7), by striking "(h)" and inserting "(i)"; and

(3) in paragraph (10), by striking "and" and inserting "or" each place it appears.

(b) EXPANDING COVERAGE OF COLORECTAL CANCER SCREENING Tests.

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS. Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) in paragraph (14), by redesigning paragraph (13) as paragraph (14); and

(B) in paragraph (15) by adding after paragraph (12) the following new subparagraph:

"(13) DRUG APC PAYMENT RATES."

(A) IN GENERAL.—With respect to payment for covered OPD services, the term 'cholesterol and other blood lipid screening tests (as defined in subsection (XX));''.

(B) SPECIFIED COVERAGE OUTPATIENT DRUG DEFINED.—

(i) I IN GENERAL.—In this paragraph, the term 'specified coverage outpatient drug' means—

(A) a radiopharmaceutical; or

(B) a drug or biological for which payment was made under paragraph (6) relating to pass-through payments, by adding at the end the following new subparagraph:

"(ii) A drug or biological for which payment was made under paragraph (6) relating to pass-through payments, by adding at the end the following new subparagraph:

"(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX));''.

(c) E FFECTIVE DATE.—The amendments made by this section apply to services furnished on or after January 1, 2004.
"(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate payment rates for palladium-103 and iodine-125 devices."

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine the payment adjustments and rates provided under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (2), and shall include such recommendations for appropriate payments for such devices.

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new paragraph:

"(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—The Secretary may not apply a functional equivalence standard (including such standard promulgated on November 1, 2002) or any other similar standard in order to deem a particular drug or biological to be identical to or similar to another drug or biological under this paragraph unless—

'(i) the Secretary develops by regulation (after providing notice and a period for public comment) criteria for the application of such standard; and

'(ii) such criteria provide for coordination with the Food and Drug Administration and require scientific studies that show the clinical relationship between the drugs or biologicals treated as functionally equivalent.

'(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of the enactment of this Act.

"(3) R EPRESENTATIVE SAMPLE OF HOSPITALS.—In conducting the study under paragraph (2), and if so, how frequently.

(d) HOSPITAL ACQUISITION COST STUDY.—

(1) IN GENERAL.—The Secretary shall conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs for which payment is made under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(rr)) for purposes of this section, unless such application was being made to such drug or biological prior to January 1, 2003.

(2) DRUGS COVERED.—The study in paragraph (1) shall not include those drugs for which the acquisition costs is less than $50 per administration.

(3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In conducting the study under paragraph (1), the Secretary shall collect data from a statistically valid sample of hospitals.

(4) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (3), and shall include recommendations with respect to the following:

(A) Whether the study should be repeated, and if so, how frequently.

(B) Whether the study produced useful data on hospital acquisition cost.

(5) COSTS DIFFER AMONG THE TYPES OF AMBULANCE PROVIDERS AND ON ACCESS, SUPPLY, AND QUALITY OF AMBULANCE SERVICES IN THOSE REGIONS AND STATES THAT HAVE A REDUCTION IN PAYMENT, regardless of where the transportation originates, the fee schedule under such subparagraph shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by 10 percent on the fee schedule under such subparagraph.

(c) INCREASE IN RENAL DIALYSIS COMPOSITE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year, the portion of the payment amount that is based on the fee schedule under such subparagraph shall be increased by the blending rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved.

"(A) For 2005 and each succeeding year, the blending rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

"(B) For 2006, the blending rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

"(C) For 2007, 2008, and 2009, the blending rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

"(D) For 2010 and each succeeding year, the blending rate shall be based 100 percent on the fee schedule under paragraph (1).

"(E) For 2013 calendar year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall determine appropriate payment amounts for each of the following

(A) as applicable to pediatric facilities.

(B) as applicable to dialysis facilities furnishing end-stage renal disease services.

(C) as applicable to dialysis facilities furnishing end-stage renal disease services.

(D) as applicable to renal dialysis facilities furnishing end-stage renal disease services.

(E) as applicable to dialysis facilities furnishing end-stage renal disease services.

(F) as applicable to dialysis facilities furnishing end-stage renal disease services.

(G) as applicable to dialysis facilities furnishing end-stage renal disease services.

(H) as applicable to dialysis facilities furnishing end-stage renal disease services.

(I) as applicable to dialysis facilities furnishing end-stage renal disease services.

(J) as applicable to dialysis facilities furnishing end-stage renal disease services.

(K) as applicable to dialysis facilities furnishing end-stage renal disease services.

(L) as applicable to dialysis facilities furnishing end-stage renal disease services.

(M) as applicable to dialysis facilities furnishing end-stage renal disease services.

(N) as applicable to dialysis facilities furnishing end-stage renal disease services.

(O) as applicable to dialysis facilities furnishing end-stage renal disease services.

(P) as applicable to dialysis facilities furnishing end-stage renal disease services.

(Q) as applicable to dialysis facilities furnishing end-stage renal disease services.

(R) as applicable to dialysis facilities furnishing end-stage renal disease services.

(S) as applicable to dialysis facilities furnishing end-stage renal disease services.

(T) as applicable to dialysis facilities furnishing end-stage renal disease services.

(U) as applicable to dialysis facilities furnishing end-stage renal disease services.

(V) as applicable to dialysis facilities furnishing end-stage renal disease services.

(W) as applicable to dialysis facilities furnishing end-stage renal disease services.

(X) as applicable to dialysis facilities furnishing end-stage renal disease services.

(Y) as applicable to dialysis facilities furnishing end-stage renal disease services.

(Z) as applicable to dialysis facilities furnishing end-stage renal disease services.

1-YEAR MORATORIUM ON THERAPY MODELS.—

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

"(a) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for Medicare beneficiaries receiving end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board composed of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

(b) REPRESENTATIVES.—Representatives referred to in paragraph (1) include representatives of the following:

(A) Patient organizations.

(B) Clinicians.

(C) The Medicare payment advisory commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b-6).

(D) The National Kidney Foundation.


(F) End-stage renal disease networks.

(G) Medicare contractors to monitor quality of care.

(H) providers of services and renal dialysis facilities furnishing end-stage renal disease services.

(I) Economists.

(K) Researchers.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

"(A) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

'(A) as applicable to pediatric facilities.

'(B) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(C) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(D) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(E) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(F) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(G) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(H) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(I) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(J) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(K) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(L) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(M) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(N) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(O) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(P) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(Q) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(R) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(S) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(T) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(U) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(V) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(W) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(X) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(Y) as applicable to dialysis facilities furnishing end-stage renal disease services.

'(Z) as applicable to dialysis facilities furnishing end-stage renal disease services.

"(B) PROMPT SUBMISSION OF OVERDUE REPORTS.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established by section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.6 percent.

SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) YEAR MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking "and 2002" and inserting "2002, and 2004".

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2003, the Secretary shall submit to Congress the report required under section 1833(g)(4) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and..."
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under section 223(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Reconciliation Act of 1999 (relating to utilization patterns for outpatient therapy).

(3) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(a) STUDY.—The Secretary shall request the National Academy of Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps under section 1874 of the Social Security Act (42 U.S.C. 1395x(g)(4)).

(b) REPORTS TO CONGRESS.—

(1) PRELIMINARY REPORT.—Not later than July 1, 2004, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1).

(2) FINAL REPORT.—Not later than September 1, 2004, the Secretary shall submit to Congress a final report on such conditions and diseases.

(c) RECOMMENDATIONS.—Not later than October 1, 2004, the Secretary shall submit to Congress a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States that require such a physician referral. The study shall—

(A) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries;

(B) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries; and

(C) analyze the potential impact on Medicare beneficiaries and on expenditures under the Medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the Medicare program.

(2) EFFECTIVE DATE.—The amendment made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS.

(a) IN GENERAL.—Section 1834(h) (42 U.S.C. 1395n(h)) is amended by striking subparagraph (C).

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 627. WAIVER OF PART B Late Enrollment Penalty for Certain Military retirees; Special Enrollment Period.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b)(42 U.S.C. 1395n(b)) is amended by adding at the end the following new sentence: "No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to enrollment periods beginning on or after January 1, 2004.

SEC. 628. Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the home.

(a) IN GENERAL.—Section 1861(g)(4) (42 U.S.C. 1395n(g)(4)) is amended by adding after subsection (a)(1) the following subsubsection:

"(i) The term 'diabetes screening tests' means diagnostic testing furnished to an individual at risk for diabetes (as defined in section 1861(y)(1)) after 'with respect to drugs and biologicals'."

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2004.


(a) COVERAGE.—Section 1858(s)(2) (42 U.S.C. 1395cc(s)(2)), as amended by sections 611 and 612, is amended—

(1) by striking "and" at the end of subparagraph (W), by striking "and" at the end of subparagraph (X), by adding "and" at the end; and

(2) by adding at the end the following new subparagraph:

"(yy) The term 'diabetes screening tests' means diagnostic testing furnished to an individual at risk for diabetes (as defined in section 1861(y)(1)) for the purpose of early detection of diabetes, including—

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate in consultation with appropriate organizations.

"(2) For purposes of paragraph (1), the term 'individual at risk for diabetes' means an individual who has any, a combination of, or all of the following risk factors for diabetes:

(A) A family history of diabetes.

(B) Overweight defined as a body mass index greater than or equal to 25 kg/m2.

(C) Habitual physical inactivity.

(D) Belonging to a high-risk ethnic or racial group.

(E) Previous identification of an elevated fasting plasma glucose.

(F) Identification of impaired glucose tolerance.

(G) Hypertension.

(H) Dyslipidemia.

"(3) The term 'diabetes screening tests' is defined to include tests, as the Secretary determines appropriate, for the following conditions:

(B) impaired fasting glucose.

"(C) HbA1c test.

"(D) Retinal examination.

"(E) Serum creatinine level.

"(F) High density lipoprotein level.

"(G) Low density lipoprotein level.

"(H) Triglyceride level.

"(I) A fasting plasma glucose test.

"(J) Other tests as defined by the Secretary.

"(2) E FFECTIVE DATE .—The amendment made by this subsection begins on the first day of the month following the month in which the individual enrolls."
“(I) History of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

“(I) Polycystic ovary syndrome.

“(3) In the case of a Medicare beneficiary, the Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of such individual.

“(b) Customer satisfaction under section 1895 of the Social Security Act (42 U.S.C. 1395ff) is amended—

(1) in paragraphs (3)(B)(ii) and (4) by striking “each fiscal year” and inserting “year” each place it appears; and

(2) in paragraph (3)(B)(ii) by striking “2004” and inserting “2007”.

(c) FREQUENCY—Section 1862(a)(1) (42 U.S.C. 1395gg(a)(1)), as amended by sections 611 and 612, is amended—

(1) in paragraph (3)(B)(ii), by striking “and” at the end of subparagraph (i); and

(2) by striking the semicolon at the end of subparagraph (K) and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(L) in the case of a diabetes screening tests or test (as defined in section 1851(yy)(2)), which is performed more frequently than is covered under section 1861(yy)(3).

(d) EFFECTIVE DATE—The amendments made by this section shall take effect on the 1st day of the calendar quarter beginning with fiscal year 2002.

(f) in paragraph (3)(B)(ii)(II), by striking “fiscal year” each place it appears and inserting “year” each place it appears.

(i) in paragraph (3)(B)(ii)(II), by striking “each fiscal year (beginning with fiscal year 2002)” and inserting “fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with fiscal year 2004)”.

(j) in paragraph (3)(B)(ii)(III), by striking “fiscal years” and inserting “years”;

(k) in paragraph (3)(B)(iii), by inserting “or year” after “the fiscal year”;

(l) in paragraph (3)(B)(iv), by inserting “or year” after “fiscal year” each place it appears;

(m) in paragraph (3)(B)(v), by inserting “or year” after “fiscal year” each place it appears;

(n) in paragraph (3)(B)(vi), by inserting “or year” after “fiscal year” each place it appears;

(o) in paragraph (3)(B)(vii), by striking “2004 and any subsequent year” and inserting “2004 and any subsequent year”;

(p) in paragraph (3)(B)(vii), by inserting “any subsequent fiscal year” and inserting “2004 and any subsequent year”;

(q) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(r) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(s) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(t) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(u) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(v) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(w) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(x) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(y) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears;

(z) in paragraph (3)(B)(vii), by inserting “or year” after “fiscal year” each place it appears.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system in section 1833 of the Social Security Act (42 U.S.C. 1395ff). Such study shall examine whether significant differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

(c) DEMONSTRATION PROJECT TO CLARIFY MEDICARE BENEFICIARY DUTIES.—

(1) DEFINITIONS.—For purposes of subsection (a), a Medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if the beneficiary—

(A) has been certified by one physician as an individual who has a permanent and severe condition that will not improve;

(B) requires to receive assistance from another individual with at least 3 of the 5 activities of daily living for the rest of the individual’s life;

(C) requires 1 or more home health services to achieve a functional condition that gives the individual the ability to leave home; and

(D) requires technological assistance or the assistance of another person to leave the home.

(2) DEMONSTRATION PROJECT SITE.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(3) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(4) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services that relates to the quality of care, patient outcomes, and additional costs, if any, to the Medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e) and shall include—

(1) an examination of whether the provision of home health services to Medicare beneficiaries under the project—

(A) adversely affects the provision of home health services under the Medicare program; or

(B) directly causes an unreasonable increase in expenditures under the Medicare program for the provision of such services that is directly attributable to such clarification.

(2) the specific data evidencing the amount of any increase in expenditures that is a directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the Medicare program; and

(3) specific recommendations to exempt permanently and severely disabled home health service recipients from the requirements on the length, frequency and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to the Medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive, in accordance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or any other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the Medicare program.

SEC. 703. AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Insurance Trust Fund under section 1411 of such Act (42 U.S.C. 1395f).

(i) DEFINITIONS.—In this section—

(1) home health beneficiary means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(2) home health services means the home health services defined in section 1861(m)(2) of such Act (42 U.S.C. 1395zz).

(3) home health beneficiary means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(4) home health services means the home health services defined in section 1861(m)(2) of such Act (42 U.S.C. 1395zz).


(t) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or any other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the Medicare program.

(2) CHRONIC CARE IMPROVEMENT.—The term ‘chronic care improvement’ means an activity that is directly attributable to the demonstration project established under this section.

(3) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or any other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the Medicare program.

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ‘activities of daily living’ means eating, toileting, transferring, bathing, and dressing.

(4) SECRETARY.—The term ‘Secretary’ means the Secretary of Health and Human Services.

Subtitle B—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

(a) DEFINITIONS.—In this section—

(1) CCIA region means an CCIA region for Medicare beneficiaries who are not enrolled under part C and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic lung disease (COPD), stroke, prostate and colon cancer, hypertension, or other condition deemed by the Secretary as appropriate for chronic care improvement.

(b) the term ‘CCIA region’ means a chronic care improvement administrative region delineated under subsection (a)(2).

(2) the term ‘CCIA region’ means an CCIA region for Medicare beneficiaries who are not enrolled under part C and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic lung disease (COPD), stroke, prostate and colon cancer, hypertension, or other condition deemed by the Secretary as appropriate for chronic care improvement.

(c) the term ‘CCIA region’ means an CCIA region for Medicare beneficiaries who are not enrolled under part C and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic lung disease (COPD), stroke, prostate and colon cancer, hypertension, or other condition deemed by the Secretary as appropriate for chronic care improvement.

(2) CHRONIC CARE IMPROVEMENT PROGRAM.—The term ‘chronic care improvement program’ and ‘program’ means such a program provided by a contractor under this section.

(b) CONTRACTOR.—The term ‘contractor’ means an entity with a contract to provide a chronic care improvement program under this Act.

(2) CONTRACTOR.—The term ‘contractor’ means an entity with a contract to provide a chronic care improvement program under this Act.

(b) CHRONIC CARE IMPROVEMENT PROGRAM.—The term ‘chronic care improvement program’ and ‘program’ means such a program provided by a contractor under this section.

(d) INDIVIDUAL PLAN.—The term ‘individual plan’ means a chronic care improvement plan established under subsection (c)(5) for an individual.

(d) INDIVIDUAL PLAN.—The term ‘individual plan’ means a chronic care improvement plan established under subsection (c)(5) for an individual.

(e) CONSTRUCTION.—Nothing in this section shall be construed as expanding the amount, duration, or scope of benefits under this title.

(f) COMPETITIVE BIDDING PROCESS.—

(1) IN GENERAL.—Under this section the Secretary shall award contracts to qualified health services companies.
entities for chronic care improvement programs for each CCIA region under this section through a competitive bidding process.

(2) PROCESS.—Under such process—

(A) the Secretary shall delineate the United States into multiple chronic care improvement administrative regions; and

(B) the Secretary shall select at least 2 (six) winning bidders in each CCIA region on the basis of the ability of each bidder to carry out a chronic care improvement program in accordance with this section, in order to achieve improved health and financial outcomes.

(3) ELIGIBLE CONTRACTOR.—A contractor may be granted a chronic improvement program, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate.

(4) CHRONIC CARE IMPROVEMENT PROGRAMS.—

(1) IN GENERAL.—Each contract under this section shall provide for the operation of a chronic care improvement program by a contractor in a CCIA region consistent with this subsection.

(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—Each contractor shall have a method for identifying Medicare beneficiaries in a region to whom it will offer services under its program. The contractor shall identify such beneficiaries through claims or other data and other means permitted consistent with applicable disclosure provisions.

(3) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary or on behalf of the Secretary and shall include information on the following:

(A) A description of the advantages to the beneficiary in participating in a program.

(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

(C) Notification that participation in a program is voluntary.

(D) A description of the method for the beneficiary to decline such participation, in which the beneficiary wishes to participate and for declining to participate and a method for obtaining additional information concerning such participation.

(4) PARTICIPATION.—A Medicare beneficiary may participate in only one program under this section and may terminate participation at any time in a manner specified by the Secretary.

(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT PLANS.—

(A) IN GENERAL.—For each beneficiary participating in a program of a contractor under this section, the contractor shall develop with the beneficiary an individualized, goal-oriented chronic care improvement plan.

(B) ELEMENTS OF INDIVIDUAL PLAN.—Each individual plan developed under subparagraph (A) shall include a single point of contact to coordinate care and the following, as appropriate:

(i) Self-improvement education for the beneficiary (such as disease self-management through medical nutrition therapy) and support education for health care providers, primary caregivers, and family members;

(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services;

(iii) With physicians and other providers to enhance communication of relevant clinical information.

(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health status;

(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

(C) CONTRACTOR RESPONSIBILITIES.—In establishing and carrying out individual plans under a program, a contractor shall, directly or through subcontractors:

(i) Guide participants in managing their health, including all their comorbidities, and in performing activities as specified under the agreement to the plan;

(ii) Use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

(iii) Develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

(6) ADDITIONAL REQUIREMENTS.—The Secretary shall establish additional requirements for programs and contractors under this section.

(7) ACCREDITATION.—The Secretary may provide that programs that are accredited by qualified organizations may be deemed to meet such requirements under this section as the Secretary may specify.

(C) CONTRACT TERMINATION .—

(1) IN GENERAL.—A contract under this section shall contain such terms and conditions as the Secretary specifies consistent with this section. The Secretary may not enter into a contract with an entity under this section unless the entity meets such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the population to be served.

(2) USE OF CONTRACTORS PERMITTED.—

(A) A contractor may carry out a program directly or through contracts with subcontractors.

(B) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment terms that require that there will not be an aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that Medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of such programs) and Medicare contract fees, shall not exceed the expenditure that would have been incurred under this title for a comparable population in the absence of any program under this section for the 3-year contract period.

(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contractor under this section may enter a risk-sharing arrangement referred to in such section.

(5) PERFORMANCE STANDARDS.—Payment to contractors under this section shall be subject to the meeting of clinical and financial performance standards set by the Secretary.

(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and report to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of:

(A) process measures, such as reductions in errors of treatment and rehospitalization rates;

(B) beneficiary and provider satisfaction;

(C) health outcomes; and

(D) financial outcomes.

(7) PHASED IN IMPLEMENTATION.—Nothing in this section is intended as preventing the Secretary from phasing in the implementation of programs.

(d) BIANNUAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress a biannual report on the implementation of this section. Each such report shall include information concerning:

(1) the scope of implementation (in terms of both regions and chronic conditions);

(2) program design;

(3) improvements in health outcomes and financial efficiencies that result from such implementation;

(4) CLINICAL TRIALS.—The Secretary shall conduct randomized clinical trials, that compare program participants with Medicare beneficiaries who are offered, but decline, to participate, in order to assess the potential of programs to—

(i) reduce costs under this title; and

(ii) improve health outcomes under this title.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, in appropriate part from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for contracts with chronic care improvement programs under this section.

(5) LIMITATION ON FUNDING.—In no case shall the funding under the Medicare+Choice program exceed $100,000,000 over a period of 3 years.

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE+CHOICE PLANS.

(a) In General.—

(1) Medicare+Choice plans are authorized to participate, in order to assess the potential of programs to—

(i) reduce costs under this title; and

(ii) improve health outcomes under this title.

(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—For purposes of this subsection the term ‘enrollee with multiple or sufficiently severe chronic conditions’ means, with respect to an enrollee in a Medicare+Choice plan offered by an Medicare+Choice organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes mellitus, stroke, cancer, hypertension, or other disease as identified by the organization as appropriate for chronic care improvement.

(3) CHRONIC CONDITIONS.—

(A) IN GENERAL.—Each chronic care improvement program under this subsection shall be conducted consistent with this subsection.

(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet the organization’s criteria for participation under the program.

(4) DEVELOPMENT OF CRITERIA.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enrollee’s consent, an individualized, goal-oriented chronic care improvement plan for chronic care improvement.

(5) ELEMENTS OF PLANS.—Each chronic care improvement plan developed under subparagraph (C) shall include a single point of contact to coordinate care and the following, as appropriate:

(A) Comprehensive case management education for the enrollee (such as education for disease management through medical nutrition therapy)
and support education for health care providers, primary caregivers, and family members.

(ii) Coordination of health care services, such as the application of a prescription drug regimen and home health services.

(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as symptom management in chronic disease, and home health self-assessment.

(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

(E) Organization responsibilities.—In establishing and carrying out chronic care improvement plans for participants under this paragraph, a Medicare+Choice organization shall, directly or through subcontractors—

(i) guide participants in managing their health, including all their co-morbidities, and in performing the activities as specified under the elements of the plan;

(ii) use decision support tools such as evidence-based practice and guidelines or other criteria as determined by the Secretary; and

(iii) develop a clinical information database to track and monitor each participant across provider settings and to evaluate outcomes.

(3) Additional requirements.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

(4) Accreditation.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

(5) SIMPLIFIED REPORT.—Each Medicare+Choice organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require.; and

(2) by amending subparagraph (I) of subsection (c)(2) to read as follows:

(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization’s chronic care improvement program under subsection (b).

(b) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning on or after 1 year after the date of the enactment of this Act.

SEC. 724. MEDPAC REPORT.

(a) MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following new paragraph:

''(2) BUDGET NEUTRALITY FOR DEMONSTRATION SEQUENCES.—Before making any recommendations, the Commission shall examine the budget neutrality for each demonstration sequence, of such recommendations, directly or through consultation with appropriate expert entities.''.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting ''the efficient provision of'' after ''expenditures for'',

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following new paragraph:

''(2) BUDGET NEUTRALITY FOR DEMONSTRATION SEQUENCES.—Before making any recommendations, the Commission shall examine the budget neutrality for each demonstration sequence of such recommendations, directly or through consultation with appropriate expert entities.''.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOTARY PARTICIPATION.—Participation in the demonstration project under this section shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 10,000.

(f) PREFERENCE IN SELECTING AGENTS.—In selecting home health agencies to participate in the demonstration project, the Secretary shall give preference to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purpose of carrying out the demonstration project, other than waiving the requirement that an individual be homebound, in order to be eligible for benefits for home health services.

SEC. 725. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project in (project) under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medical beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for the provision of home health services that would otherwise be provided in the beneficiary’s home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 U.S.C. 1395f(k)), to the extent that such amount is a home health agency, or a medical adult day care facility arrangement with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amounts of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395f(k)) to reflect any decreases in amounts expended from the Trust Funds as a result of the demonstration project conducted under this section.

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 States selected by the Secretary that license or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation in the demonstration project under this section shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 10,000.

(f) PREFERENCE IN SELECTING AGENTS.—In selecting home health agencies to participate in the demonstration project, the Secretary shall give preference to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as are necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound, in order to be eligible for benefits for home health services.

SEC. 726. EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later than 30 months after the commencement of the project, the Secretary shall submit a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and cost effectiveness of the demonstration project, other than waiving the requirement that an individual be homebound, in order to be eligible for benefits for home health services.

(2) Such recommendations regarding the extension, expansion, or termination of the proposal.
(a) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(b) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(c) other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term "medicare beneficiary" means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to examine each national coverage determination to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(2) LOCAL COVERAGE DETERMINATION PROCESS.—With respect to local coverage determinations made on or after January 1, 2004—

(A) PLAN TO PROMOTE CONSISTENCY OF LOCAL COVERAGE DETERMINATIONS.—The Secretary shall consult with appropriate outside clinical experts.

(B) LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the terms 'local coverage determination' and 'local coverage determination' have the meaning given such terms in paragraphs (2)(B)(1)(B) and (2)(B), respectively, of section 1861(s).

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national and local coverage determinations as of January 1, 2004.

(b) MEDICAID COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, which payment is made to the hospital under section 1886(d), the Secretary shall—

(A) determine that, in the case of a request for a national coverage determination, assign or temporary coverage of, and payment for, a medical device exemption by the Food and Drug Administration (except as may be necessary to implement paragraph (b));

(B) meet such criteria as the Secretary determines appropriate; and

(C) make a final decision on the request within 100 days of the conclusion of the 30-day period referred to in subparagraph (B).

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall apply to clinical trials begun before, on, or after the date of enactment of this Act and to items and services furnished on or after such date.

(c) ISSUE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall issue revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.
SEC. 735. MEDICARE PANCREATIC ISLET CELL TRANSPLANT DEMONSTRATION PROJECT.
(a) Establishment.—In order to test the appropriateness of pancreatic islet cell transplantation, not later than 120 days after the date of the enactment of this Act, the Secretary shall establish a demonstration project which the Secretary, provides for payment under the Medicare program under title XVIII of the Social Security Act for pancreatic islet cell transplantation and related items and services in the case of Medicare beneficiaries who have type I (juvenile) diabetes and have end stage renal disease.

(b) Authorization.—The authority of the Secretary to conduct the demonstration project under this section shall terminate not later than 5 years after the date of the establishment of the project.

(c) Evaluation and Report.—The Secretary shall conduct an evaluation of the outcomes of the demonstration project. Not later than 120 days after the date of the termination of the demonstration project under subsection (b), the Secretary shall submit to Congress a report on the project, including recommendations for such legislative and administrative action as the Secretary deems appropriate.

SEC. 901. CONTINUATION OF MEDICAID DSH ALLOTMENTS UNDER BIPA 2000.
(a) In General.—Section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f))—
(1) in paragraph (2)—
(A) in the heading, by striking "THROUGH 2002" and inserting "THROUGH 2000";
(B) by striking "ending with fiscal year 2002" and inserting "ending with fiscal year 2000";
and
(C) in the table in such paragraph, by striking the columns labeled "FY 02" and "FY 03";
(2) in paragraph (3)(A), by striking "ending with fiscal year 2002" and inserting "ending with fiscal year 2000"; and
(3) in paragraph (3)(B), by striking the table labeled "FY 02" and "FY 03".
(b) Effectiveness.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act. The amendments made by paragraph (1) shall take effect on the date of the establishment of the project.

SEC. 902. INCREASE IN FLOOR FOR TREATMENT OF AN EXTREMELY LOW DSH STATE TO 3 PERCENT IN FISCAL YEAR 2003.
(a) Increase in DSH Floor for Fiscal Year 2003.—Section 1923(f)(5) of the Social Security Act (42 U.S.C. 1396r–4(f)(5)) is amended—
(1) by striking "fiscal year 1999" and inserting "fiscal year 2003";
(2) by striking "August 31, 2000" and inserting "August 31, 2002";
(3) by striking "1 percent" each place it appears and inserting "3 percent"; and
(4) by striking "fiscal year 2001" and inserting "fiscal year 2003".
(b) Effective Date.—The amendments made by subsection (a) shall take effect as if enacted on October 1, 2002, and apply to DSH allotments under title XIX of the Social Security Act for fiscal year 2003 and each fiscal year thereafter.

SEC. 903. CLARIFICATION OF INCLUSION OF IN-PATIENT DRUG PRICES CHARGED TO MEDICAID HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM.
(a) In General.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by striking the heading thereof and inserting the following:
"(including inpatient prices charged to hospitals described in section 3408(a)(4)(L) of the Public Health Service Act)"
(b) Effective Date.—The amendment made by paragraph (a) shall take effect on the date of the enactment of this Act.

SEC. 904. PROHIBITION AGAINST THE USE OF FUNDS TO PERFORM OR ASSIST IN THE PERFORMANCE OF ABORTIONS.
(a) In General.—Section 1903(j) of the Social Security Act (42 U.S.C. 1396a(j)) is amended by striking "fiscal year 2001" and inserting "fiscal year 2002".
(b) Effective Date.—The amendment made by subsection (a) shall take effect as if enacted on the date of the enactment of the Balanced Budget Act of 1997 (Public Law 104–208).
(2) **Effective date.**—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) **SPECIAL AND REGULATORY INCONSISTENCIES.**—Section 1871 (42 U.S.C. 1399h), as amended by section 902(a), is amended by adding at the end the following:

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"(f) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress and Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and
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(c) The amendment made by paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation and regulations that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

**Subtitle B—Contracting Reform**

SEC. 911. **INCONSISTENCIES IN MEDICARE ADMINISTRATION.**

(a) **Consolidation and Flexibility in Medicare Administration.**—

(1) **In General.**—Title XVIII is amended by inserting after section 1874 the following new section:

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"(c) **Provision of Technical Assistance.**—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.
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(2) **Eligibility of Entities.**—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

(b) **Application of Federal Acquisition Regulation.**—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

(c) **Use of Competitive Procedures.**—

(1) **In General.**—Except as provided in laws with general applicability to Federal acquisition and procurement or in subpart 8 of part 18 of this title, the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors.
under this section, taking into account performance quality as well as price and other factors.

(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a Medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the Medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract during the prior performance period, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among Medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the provider of services and suppliers affected by such transfer, and contact information for the contractors involved).

(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for Medicare administrative contractors to provide quality service and to promote efficiency.

(2) PERFORMANCE REQUIREMENTS.—No contract under this section shall be entered into with any Medicare administrative contractor unless the Secretary finds that such Medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal compliance, management of services, and other matters as the Secretary finds pertinent.

(3) PERFORMANCE REQUIREMENTS.

(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

(B) CONSULTATION.—In developing such requirements, the Secretary may consult with the providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, and representatives of organizations performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(C) CONTRACTS.—All contract performance requirements shall be set forth in the contract between the Secretary and the appropriate Medicare administrative contractor. Such performance requirements—

(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a Medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information as the Secretary may request and may find necessary in performing his functions under this title; and

(B) to maintain such records and afford such other facilities as the Secretary may request in order to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

(5) SURETY BOND.—A contract with a Medicare administrative contractor under this section shall be conditioned on the contractor providing a bond, in such face amount and conditioned as the Secretary shall determine, with the contractor, any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or certifying the work performed under the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(C) TERMS AND CONDITIONS.—

(1) IN GENERAL.—A contract with any Medicare administrative contractor under this section may contain such terms and conditions that are necessary and proper and may provide for advances of funds to the Medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the Medicare administrative contractor match data obtained other than in its activities under this title with data in the administrative contractor's possession or identify situations in which the provisions of section 182(b) may apply.

(3) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.

(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payment certified by the individual under this section.

(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.

(A) IN GENERAL.—No Medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the Medicare administrative contractor acted with reckless disregard of its obligations under its Medicare administrative contract or with intent to defraud the United States.

(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of section 3729 through 3731 of title 31, United States Code (commonly known as the 'False Claims Act').

(4) INDEMNIFICATION BY SECRETARY.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a Medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising out of or relating to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and necessary to protect the specific obligations of the Medicare administrative contractor, indemnify the contractor and such persons.

(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined to be fraudulent or criminal by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to such liability before the Secretary finds that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements, (subject to subparagraph (B)), and costs (including reasonable legal expenses).

(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph is conditioned upon prior written approval by the Secretary of the final settlement or compromise.

(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) to change any common law immunity that may be available to a Medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.

(2) CONSIDERATION OF INCLUSION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1816(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and appeals hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (21 U.S.C. 1395n).—Section 1816 (42 U.S.C. 1395n) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART A:"

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with Medicare administrative contractors under section 1874A:"

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking "agreement under this section" and inserting "contract under section 1874A that provides for making payments under this part:"

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking "An agreement with an agency or organization under this section" and inserting "A contract with a Medicare administrative contractor under section 1874A with respect to the administration of this part:"; and
(B) by striking “such agency or organization” and inserting “such medicare administrative contractor” each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows: “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B.”

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B); and

(ii) in subparagraph (C), by striking “carriers” and inserting “medicare administrative contractors”;

and

(iii) by striking subparagraphs (D) and (E); and

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking “Each such contract shall provide that the carrier” and inserting “The Secretary”;

(ii) by striking “will” the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), (J), and (K) of section 1874A (10 U.S.C. 2812); and

(iii) in subparagraph (B), in the matter before clause (i), by striking “to the policyholders and subscribers of the carrier” and inserting “to the policyholders and subscribers of the medicare administrative contractor”;

(iv) by striking subparagraphs (C) and (D); and

(E) in paragraph (4)(A)(i), by striking “the medicare administrative contractors under section 1874A(a)(3)(B)” and inserting “medicare administrative contractors”;

(F) in paragraph (5)(A)(i), by striking “the medicare administrative contractors” and inserting “medicare administrative contractors”;

(G) in paragraph (5)(B), by striking “each carrier” and inserting “carrier”;

(H) in paragraph (5)(C)(i), by striking “the medicare administrative contractors” and inserting “medicare administrative contractors”;

(I) in paragraph (6)(A)(i), by striking “each medicare administrative contractor” and inserting “medicare administrative contractor”;

(J) in paragraph (6)(B)(ii), by striking “the medicare administrative contractors” and inserting “medicare administrative contractors”;

(K) in paragraph (6)(B)(vii), by striking “the medicare administrative contractors under this section (a)” and inserting “medicare administrative contractors having a contract under section 1874A that provides for making payments under this part”;

(L) by striking “such carrier” and inserting “medicare administrative contractor”;

(M) by striking paragraph (7) and inserting “The Secretary shall take such steps, consistent with the demonstration projects and contracts and contractors.”

(N) in paragraph (8)(A), by striking “the medicare administrative contractors” and inserting “medicare administrative contractors under section 1874A.”

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking “contract under this Act, other than under this section (a)” and inserting “contract under section 1874A that provides for the disbursement of funds, as described in section (a)(1)(B)”;

(C) in paragraph (3)(A), by striking “section 1874A that provides for making payments under this part;” and

(D) in paragraph (3)(B), by striking “section 1874A(a)(3)” and inserting “section 1874A(a)(3)(B)”.

(5) In paragraph (4), in the matter preceding subparagraph (A), by striking “carrier” and inserting “medicare administrative contractor”;

and

(E) by striking subparagraphs (5) and (6).

(6) Subsection (g) is amended by striking “carrier or carriers” and inserting “medicare administrative contractor or contractors”.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking “Each carrier having an agreement with the Secretary under subsection (a)” and inserting “The Secretary”;

and

(ii) by striking “such carrier” and inserting “the Secretary”;

and

(B) in paragraph (3)(A), by striking “such carrier having an agreement with the Secretary under subsection (a)” and inserting “medicare administrative contractor having a contract under section 1874A that provides for making payments under this part;” and

(C) in paragraph (3)(B)—

(i) by striking “a carrier” and inserting “a medicare administrative contractor” each place it appears;

(ii) by striking “the carrier” and inserting “the contractor” each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking “medicare administrative contractors” each place it appears.

(8) Subsection (i) is amended—

(A) in paragraph (1)(A)(iii), by striking “carrier” and inserting “medicare administrative contractor”;

and

(B) in paragraph (2), by striking “carrier” and inserting “medicare administrative contractor”.

(9) Subsection (j)(3)(A) is amended by striking “each medicare administrative contractor” in clause (i); and

(10) Subsection (j)(1)(A) is amended by striking “carrier” and inserting “carrier”.

(D) EFFECTIVE DATE; TRANSITION RULE.—

(1) E NFORCEMENT.—The provisions of this section shall apply to contracts entered into on or after October 1, 2009, and after which the Secretary has modified oversight and management of medicare administrative contractors.

(2) TRANSITION RULES.—The provisions of this section shall apply to contracts entered into before such date; and

(A) a timeline for complete transition to full competition;

(B) a detailed description of how the Secretary has modified oversight and management of medicare administrative contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) In General.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

“(2) REQUIREMENTS FOR INFORMATION SECURITY.—

“(A) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contract and contractor wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title.

(B) C ONSTR UCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to apply on or after October 1, 2009.

(C) C ONSTR UCTION FOR NEW CONTRACTS.—The amendments made by this section shall take effect on October 1, 2010.

(D) WAIVER.—The Secretary shall take such steps, consistent with subparagraphs (A) and (B) of section 1874A(a)(3) (relating to determining and making payments) shall implement a contract and contractor wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title.

(E) INDEPENDENT AUDITS.—

“(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of section 1874A(a)(3) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor and the contractor's contracts under this section. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) be submitted to the Secretary with respect to such functions under this title.
such evaluations.

(2) DEADLINE FOR INITIAL EVALUATION.—

(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously been assessed for under section 3502(8) of title 44, United States Code, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable internal control standards promulgated under section 11311 of title 40, United States Code.

(ii) Ongoing contractors.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant to paragraph (a) shall be completed prior to commencing such functions.

(3) REPORTS.—

(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services to the Secretary.

(ii) TO CONGRESS.—The Inspector General of the Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(f) of the Social Security Act (as added by paragraph (1), and as amended by section 912(a)(1) and as amended by section 912(a)(2), as amended by adding at the end the following new subsection:

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORTS.—By not later than December 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the methodologies in assessing medicare contractors in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.

(c) PRIORITY FOR FISCAL INTERMEDIARIES AND CARRIERS.—

The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary and each carrier under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

(i) COMMUNICATIONS WITH BENEFICIARIES.—The Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(ii) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than 90 days after the date on which the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractors' performance and the extent to which the Secretary will implement the methodologies for medicare contractors in order to give such contractors an incentive to implement effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect Octo-

ber 1, 2004.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—The Secretary shall provide, for those providers of services and suppliers who submit claims for medicare claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a timely manner, and to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the accuracy, consistency, and timeliness of the information so provided.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORTS.—

(i) IN GENERAL.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers who submit claims for medicare claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, and for those individuals entitled to benefits under part A or enrolled under part B, or both, concerning the accuracy, consistency, and timeliness of the information so provided.

(ii) RESPONSIBILITY.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to questions related to medicare administrative contractors under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(iii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect Octo-

ber 1, 2004.
Supplementary Medical Insurance Trust Fund $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

(2) Use.—The funds made available under paragraph (1) shall be used to increase the conduct by medi care contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

(c) Tailoring Education and Training Activities for Small Providers or Suppliers.—

(1) In general.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

(2) Small provider of services or supplier.—In this subsection, the term ‘small provider of services or supplier’ means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) Effective date.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) Requirement to Maintain Internet Sites.—

(1) In general.—Section 1889, as added by subsection (a), is further amended by striking the word ‘in’ from the beginning of subsection (b), is further amended by adding at the end the following new subsection:

(d) Internet sites; FAQs.—The Secretary shall maintain on the Internet site developed under paragraph (d) at such time as the Secretary shall determine program compliance and to suggest small providers of services or suppliers how to meet the special needs of small providers of services or suppliers to develop and maintain an Internet site which—

(A) provides answers in an easily accessible format to frequently asked questions, and

(B) includes other published materials of the contractor, that relate to providers of services and suppliers under the programs under this title and such services or suppliers (as defined in paragraph (2)) as it relates to such programs.

(2) Effective date.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) Additional Provider Education Provisions.—

(1) In general.—Section 1899, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsection:

(e) Encouragement of Participation in Education Program Activities.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(2) Effective date.—Nothing in this section or section 1899(g) shall be construed as providing for disclosure by a medicare contractor, a medicare contractor conducting an audit of the identity of any provider or supplier, or the Federal Insurance Trust Fund, or by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(3) Definition.—For purposes of this subsection, the term ‘medicare contractor’ includes the following:

(A) a Medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842;

(B) an eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.

(2) Effective date.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) Establishment.—The Secretary shall establish a demonstration program in this section referred to as the ‘demonstration program’ under section 1893 of the Social Security Act (including provisions of title XI of such act as so specified) under which technical assistance described in paragraph (2) is available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such act as so specified).

(b) Form of Technical Assistance.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursements.

(c) Small Providers of Services or Suppliers.—In this section, the term ‘small provider of services or supplier’ means—

(A) a provider with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) Qualification of Contractors.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified contractors (as determined by the Secretary) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity’s work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(e) Description of Assistance.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(f) Avoidance of Recovery Actions for Problems Identified as Corrected.—The Secretary shall provide that, absent evidence to the contrary, any violation of law, any errors found in a compliance review for a small provider of services or supplier that corrects the problems identified as requiring correction under the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to the satisfaction of the Secretary within 30 days of the date of the visit by the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

(g) Definitions.—For purposes of this section, the term ‘medicare provider’ includes the following:

(1) a medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842;

(2) an eligible entity with a contract under section 1893.

(3) in paragraph (1), as so redesignated by section 5(f)(1)

(4) in section 1899(g) of the Social Security Act, as inserted by section 5(f)(1) with appropriate expertize with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity’s work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(5) in this subsection.

(b) Medicare Provider Ombudsman.—The Secretary shall apoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

(1) provide assistance on a confidential basis to providers of services and suppliers with respect to complaints, grievances, and, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations related to suspending program activities); and

(3) in this subsection.

(b) Medicare Provider Ombudsman.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

(1) provide assistance on a confidential basis to providers of services and suppliers with respect to complaints, grievances, and, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations related to suspending program activities); and

(3) in this subsection.

(b) Medicare Provider Ombudsman.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

(1) provide assistance on a confidential basis to providers of services and suppliers with respect to complaints, grievances, and, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations related to suspending program activities); and

(3) in this subsection.
"(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(b) MEDICARE BENEFICIARY OMBUDSMAN.—

"(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, to the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to a representative of such program to seek information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

"(2) provide assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; from a Medicare+Choice plan under part C; and

"(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 430 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) FUNDING.—There are authorized to be used for the Medicare Beneficiary Ombudsman, as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1805(e)(2)(B) is amended by adding at the end the following: "The Secretary shall provide, through the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to a representative of such program to seek information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

(2) COMPRESS A REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding medicare programs.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas of at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices or areas with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—

The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area, or both.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION.—

(1) IN GENERAL.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of:

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided under section 1861(ee)(2)(B) of the Social Security Act, the Secretary shall include information to the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the general public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "'hospice'" and inserting "'hospice care service,'" and

(B) by inserting before the period at the end the following: "and, in the case of individuals referred to in subsection (a) with, and

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 927. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2005, the Commissioner of Social Security shall transfer the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the respective Commissioner of Social Security and the Secretary of Health and Human Services.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described
in such subsection from the Social Security Administration to the Secretary.

(2) Assuring Independence of Judges.—The Secretary shall assure the independence of administrative law judges by appointing administrative law judges. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another other officer of the Administration.

(3) Geographic Distribution.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) Hiring Authority.—Subject to the amounts provided in advance in appropriations Acts, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling Medicare cases, subject to paragraph (2), and to hire support staff for such purposes.

(5) Financing.—Amounts payable under the law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) Shared Resources.—The Secretary shall enter into such arrangements with the Commissioner for administrative law judges and their staffs under subsection (b)(4); and (b) by adding at the end the following new paragraph:

(2) Expedited Access to Judicial Review.—(A) In General.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to the same question of law or regulation in a case of appeal.

(B) Prompt Determinations.—If, after or coincident with appropriately filing a request for access to judicial review, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matter in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials required the Secretary shall make a determination on the request in writing within 60 days after receipt of the request.

(C) Access to Judicial Review.—(i) In General.—If the appropriate review panel determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

(ii) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

(D) Deadline for Filing.—Such action shall be filed, in the case described in

(i) within 60 days of the date of the determination described in such subparagraph; or

(ii) clause (ii), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(E) Venue.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located or, in the case of a right of action that is joined by more than one applicant, the judicial district in which the great number of applicants are located, and not subject to review by any other court.

(F) Interest on Amounts in Controversy.—Where a provider of services or supplier is entitled to judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) Expedited Access to Judicial Review.—(1) In General.—(A) (42 U.S.C. 1395gg(b)) as amended by BIPA, is amended—

(2) by striking “(4)”; and

(3) by adding at the end the following new paragraph:

(4) Expediting Review of Certain Provider Agreement Determinations.—(2) by adding at the end the following new subparagraph:

(4) Authorizing and Early Presentation of Evidence.—(1) In General.—(3) by adding at the end the following new paragraph:

(2) Review Panels.—For purposes of this subparagraph, a ‘review panel’ consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a Medicare independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.
"(3) Requiring full and early presentation of evidence by providers.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented in the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 10, 1999.

(b) USE OF PATIENT'S MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by adding at the end the following new subparagraph:

(4) REQUIREMENTS OF NOTICE OF DETERMINATION.—With respect to an initial determination insofar as it results in a denial of a claim for benefits or redetermination:

(A) the written notice on the determination shall include—

(i) the specific reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

(5) REQUIREMENTS OF NOTICE OF REDETERMINATION.—With respect to a redetermination insofar as it results in a denial of a claim for benefits or redetermination:

(A) the written notice on the redetermination shall include—

(i) the specific reasons for the redetermination; and

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate) after "in writing,"; and

(B) by inserting "and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section" after "such decision.".

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) by striking "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate) after "in writing,"; and

(B) by adding at the end the following new paragraph:

(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) by striking "Prepare and submit to the Secretary..." and inserting "Prepare, by striking "Prepare and submit to the Secretary..." and

(B) by adding at the end the following new subparagraph:

(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be a physician (allopathic or osteopathic), a physician (allopathic or osteopathic), and neither party objects; and

(D) Q UALIFIED INDEPENDENT CONTRACTORS.—

(A) Eligibility requirements for independent contractors.—Section 1869(c)(3)(C) (42 U.S.C. 1395ff(c)(3)(C)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new subparagraph:

(2) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in subsection (g)(5));

(ii) not have a material familial, financial, or professional relationship with such a party; and

(iii) not otherwise have a conflict of interest with such a party.

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or other contractor and provides services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) in paragraph (1), by striking "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new paragraph:

(2) RECONSIDERATIONS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new subparagraph:

(2) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party; and

(iii) not otherwise have a conflict of interest with such a party.

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(ii) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(i) the individual is not involved in the provision of items or services in the case under review;

(ii) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party object; and

(iii) the individual is not an employee of the intermediary, carrier, or other contractor and provides services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this subsection shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is appropriately credentialed or licensed in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue.
"(S) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits or services or documentation under part B, or both, any of the following:—

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative) of the health care professional that provides the items or services involved in the case.

(C) The health care professional that provides the items or services (or treatment) involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(F) Any other party determined under any regulations to have a substantial interest in the case involved."

3. REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395f(c)(4)) is amended by striking "12 qualified independent contractors under this subsection" and inserting "a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reviews and determinations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a threshold upon the differences in the circumstances triggering prepayment review."

4. EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

5. TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2), any reference to a medicare administrative contractor shall be deemed to include a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

6. RECOVERY OF OVERPAYMENTS.—

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395dd) is amended by adding at the end the following new subsection:—

"(f) RECOVERY OF OVERPAYMENTS.—

(1) USE OF REPAYMENT PLANS.—

(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of the amount overpaid under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier, the Secretary may order or into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months, may request that the provider enter into a plan with the Secretary to repay the overpayment amount, such payment amount shall be taken into account under clause (i) with respect to such a termination date based upon the differences in the circumstances triggering prepayment review.

(B) HARDSHIP.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

(i) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(ii) in the case of another provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice under the provisions of section 1869(b)(2), the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title;

(ii) there is an indication of fraud or abuse committed against the program;

(iii) the immediate collection of violation of repayment plan, if a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(F) LIMITATION ON RECOVERY.—

"(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action against any other person, including any medicare contractor, as defined in subparagraph (C) to recoup the overpayment until the date the decision on the reconsideration has been rendered.

"(B) COLLECTION WITH INTEREST.—No amount recovered shall accrue interest (as defined in such section) or otherwise unless—

(i) the amount overpaid, a medicare contractor may recover the overpayment from such person, the aggregate amount of the overpayment exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the cost reporting period covered by the most recently submitted cost report; or

(ii) there is an indication of fraud or abuse committed against the program.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' means, with respect to a claim previously overpaid, a medicare contractor that was not paid under this title during the previous year or was paid under this title only during a portion of the previous year.

(D) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were determined to be overpaid, a mediator contractor may request the periodic production of records or documentation for a
limited sample of submitted claims to ensure that the previous practice is not continuing.

'(5) CONSENT SETTLEMENT REFORMS.—

'(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

'(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—If, in a consent settlement offer made to a provider of services or supplier a consent settlement, the Secretary shall—

' (i) communicate to the provider of services or supplier—

'(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

'(II) the nature of the problems identified in such evaluation; and

'(iii) the steps that the provider of services or supplier should take to address the problems; and

'(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

'(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(iii). Taking into account such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

'(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

'(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

'(I) the opportunity for a statistically valid random sample; or

'(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

'(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term ‘consent settlement’ means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a valid random sample of claims and the provider of services or supplier agrees not to appeal the claim involved.

'(E) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractors in cases in which the contractor has identified certain billing codes that may be overutilized by that class of providers of services or suppliers under the programs under this title (to the extent provisions of title XI insofar as they relate to such programs).

'(F) PAYMENT AUDITS.—

'(A) WRITTEN NOTICE FOR POST-PAYMENT AUDIT.—Subject to subparagraph (C), if a Medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

'(B) IDENTIFICATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a Medicare contractor audits a provider of services or supplier under this title, the contractor shall—

' (i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

'(ii) inform the basis, by the provider of services or supplier of the appeal rights under this title as well as consistent settlement options (which are at the discretion of the Secretary); and

'(iii) offer the provider of services or supplier an opportunity to provide additional information to the contractor; and

'(iv) take into account information provided, on an as-applied basis, by the provider of services or supplier under clause (iii).

'(C) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

'(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term ‘consent settlement offer’, means an offer to settle a projected overpayment after the date of the enactment of this Act.

'(E) EFFECTIVE DATES AND DEADLINES.—

'(1) USE OF REPAYMENT PLANS.—Section 1893(f)(2) of the Social Security Act, as amended by subsection (a)(2), shall apply to repayments made after the date of the enactment of this Act.

'(2) CONSULTATION.—Section 1866(e)(3)(C) of the Social Security Act, as amended by subsection (a)(2), shall apply to consultations entered after the date of the enactment of this Act.

'(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as amended by subsection (a)(2), shall apply to extrapolations initiated after the date that is 1 year after the date of the enactment of this Act.

'(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as amended by subsection (a)(2), shall take effect on the date of the enactment of this Act.

'(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as amended by subsection (a)(2), shall apply to consent settlements entered into after the date of the enactment of this Act.

'(6) NOTICE OF OVER-UTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall establish the process for the overutilization of billing codes under section 1893(f)(6) of the Social Security Act, as amended by subsection (a)(2).

'(7) PAYMENT AUDITS.—Section 1893(f)(7) of the Social Security Act, as amended by subsection (a)(2), shall apply to audits initiated after the date of the enactment of this Act.

'(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall establish a standard methodology for selecting claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as amended by subsection (a)(2).

SEC. 838. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

'(A) IN GENERAL.—Section 1866(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (I) the following: "(E) ENROLLMENT PROCESSES;"

'(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of Medicare administrative contractors in meeting the deadlines established under this subparagraph.

'(C) CONSULTATION.—Before offering a provider of services or supplier enrollment forms.—The Secretary shall consult with providers of services and suppliers before making changes in the provider of services or supplier enrollment forms that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

'(D) EFFECTIVE DATES.—

'(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section (a)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

'(2) CONSULTATION.—Section 1866(e)(3)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

'(E) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

'(F) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

'(1) IN GENERAL.—Section 1896(d)(10)(D)(vi) is amended by adding after subclause (II) the following: "(E) PROVING REMEDIATION WITHOUT PURSUING APPEALS PROCESS."

'(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate Medicare contractors (as defined in section 1899(g) of the Social Security Act, as added by section 303(a)(1)) and representatives of providers of services and suppliers, a process that, in the case of material misrepresentations (as defined by the Secretary) that are detected in the submission of claims under the Medicare programs under this Act, permits a provider of services or supplier to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to result in corrected claims.

'(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

'(1) IN GENERAL.—Section 1896(d)(10)(D)(vi) is amended by adding after subclause (I) the following: "Notwithstanding subclause (I), a hospital may submit (or resubmit) an application for a change in subclause (II) of such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled."

'(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

'(G) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

'(A) IN GENERAL.—Notwithstanding any other provision of this Act, in fiscal year 2004, a provider of services or supplier may submit (or resubmit) an application for a change described in section 1896(d)(10)(C)(ii)(I) of the Social Security Act for fiscal year 2004 if the Secretary demonstrates to the satisfaction of the Secretary that the use of corrected or supplementary data under
the amendment made by paragraph (1) would materially affect the approval of such an application.

(b) Application of Budget Neutrality.—If one or more of the hospital’s applications are approved as a result of paragraph (1) and subparagraph (A) of §1869(f)(2)(D), the hospital shall return to the Secretary of Health and Human Services the amounts corresponding to the hospital’s share of the effects on the sustainable growth rate under such section as determined in accordance with the provisions of such section.

(c) Application of Budget Neutrality.—If the provider requests to have the item or service that is the subject of the request included in paragraph (1)(B)(iii), the Secretary may, in accordance with the provisions of such section, make a determination as to whether the item or service is covered under this subsection and subject to adjustment for purposes of this subsection and subject to adjustment for purposes of this subsection. In making such a determination, the Secretary may require that the request be accompanied by a description of the request for determination described in paragraph (1)(B)(iii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) Response to Request.—

(a) In General.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to—

(i) the item or service is so covered;

(ii) the item or service is not so covered;

or

(iii) the contractor lacks sufficient information to make a coverage determination.

(b) Deadline to Respond.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under such subsection (a)(2)(A).

(c) Informing Beneficiary in Case of Physician Request.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be given a determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service.

(5) Effect of Determination.—

(a) Binding Nature of Positive Determination.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(b) Notice and Right to Redetermination in Case of a Denial.—In General.—If the contractor makes the determination described in paragraph (4)(A)(ii),

(i) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered;

(ii) the contractor shall include in notice under paragraph (4)(A)(ii) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

(iii) Deadline for Redeterminations.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of a determination relating to a claim for benefits under subsection (a)(3)(C)(iii).

(iv) Limitation on Further Review.—

(a) In General.—Subsection (a) shall apply to determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims, to subject further administrative appeal or judicial review under this section or otherwise.

(b) Decision Not to Seek Prior Determination or Negative Determination Does Not Fit Right to Obtain Services, Seek Reimbursement, or Appeal Rights.—Nothing in this subsection shall be construed as affecting the right of the individual who

(i) decides not to seek a prior determination under this subsection with respect to items or services or;

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii), from receiving (and submitting a claim for) such items and services and from obtaining administrative or judicial review respecting such claim under the otherwise applicable provisions of this Act.

(c) No Prior Determination After Receipt of Services.—Once an individual is provided items and services, failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review respecting such items or services.

(6) Effective Date; Transition.—

(a) Transition.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medica care administratoors, any reference in section 1869(g) of such Act (as added by such amendment) to a reference to a fiscal intermediary or carrier with an agreement under section 1816, or a contract under section 1842, respectively, of such Act.

(b) Effective Date; Transition.—

(1) Data Collection.—The Secretary shall establish a program for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(c) Provisions Relating to Advance Beneficiary Notices; Report on Prior Determination Process.—

(a) In General.—Subject to paragraph (2), eligible items and services are items and services which are physicians’ services, drugs, and other items and services set forth in section 1886 of the Act. The establishment of such a program shall be provided in the legislation concerning the providers of services and other persons on the approval of advance beneficiary notices and coverage policies under the medicare program.

(b) GAO Report Report on Use of Advance Beneficiary Notices.—The Secretary shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information on the use of advance beneficiary notices and information on such notices and the response of beneficiaries to such notices.

(c) GAO Report Report on Use of Prior Determination Process.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under such procedures, and the number of such procedures resulting from the application of such process; and
(b) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required for visits is burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term ‘advance beneficiary notice’ means a written notice on how to notify Medicare beneficiaries that payment for claims filed as part of the pilot project and lasting only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

Vote for Title XVIII of such Act before items or services under such title.

Title XVII—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (1) and (2) within the Centers for Medicare & Medicaid Services (in this section referred to as ‘CMS’).

(c) COMPOSITION.—The Council shall be composed of senior CMS staff and physicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (9)).

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations for such visits in a manner that takes into account the amount of time the physician spends with the patient.

(f) DEFINITIONS.—In this section—

(1) the term ‘rural area’ has the meaning given that term in section 1866(d)(2)(D) of the Act.

(2) the term ‘teaching setting’ means a facility where physicians bill under physicians’ fee-for-service arrangements for Medicare services furnished to trainee physicians.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1866(b)(6)(C) of the Act (42 U.S.C. 1395ww(d)(2)(B)) is amended by inserting at the end the following new subsection:

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h)(42 U.S.C. 1395l(h)) is amended by adding at the end the following:

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as ‘new test’).

(9) DETERMINATIONS UNDER SUBPARAGRAPH.—(A) The Secretary shall make available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which there is no payment under this subsection for a year.

(10) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the report under subparagraph (A) and submit a report on such analysis to Congress.
(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in the payment of the amounts, receive such comments and recommendations (and data on which the recommendations are based); (iv) after such public meeting, comments and (other than proprietary data) considered in making such determinations, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under paragraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments and responses to comments and suggestions received from the public.

The Secretary in implementing this subsection as the Secretary deems appropriate, for purposes of this paragraph:

(i) the term ‘HCPCS’ refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be ‘substantially revised’ if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing specific test).

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using data from federal, state, and local health systems, or any other methods and sources. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics, that collect data relevant to this purpose, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) PROCESS FOR ADOPTION OF ‘ICD CODES AS DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d-1(f))) is amended by inserting after the first sentence the following:

‘Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this section, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System (‘ICD-10-PCS’) and the International Classification of Diseases, 10th Revision, Clinical Modification (‘ICD-10-CM’) as a standard under this part for the reporting of diagnoses, the Secretary may implement the Secretaries of Health and Human Services’.
(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory groups, members of which are established (within the Department of Health and Human Services or otherwise).

SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395u(dd)(5)) is amended by adding at the end the following:

"(ii) provided in an arrangement under this title where the hospice program for the provision by that other program of services described in paragraph (2)(A)(iii)(II) shall apply with respect to the services provided under such arrangement.

"(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a type or nature that may not be provided non-routinely and so infrequently so that the provision of such services directly would be impractical and prohibitively expensive.";

(b) CONFORMING PAYMENT PROVISION.—Section 1867(i)(4) (42 U.S.C. 1395f(i)(4)) is amended by adding at the end the following new paragraph:

"(4) In the case of a hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1395cc (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking "and" at the end and inserting "or"; and

(B) in subparagraph (S), by striking the period at the end and inserting "; and";

and

(C) by inserting after subparagraph (S) the following:

"(T) In the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.130 of title 29 of the Code of Federal Regulations (as or subsequently redesignated); and"

and

(2) by adding at the end of subsection (b) the following new paragraph:

"(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

"(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (T) of this section that is subject to the provisions of such Act.

"(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as such a penalty under subsection (a) of section 1128A as are imposed and collected under that section.".

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1395ww(d)(5)(C)) is amended—

(A) by striking section 1162 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1162 (42 U.S.C. 1395w(d)(5)(E)) is amended—

(A) in the last sentence of subsection (a), by striking "established under section 1114(f)"); and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking "subsection (j)"; and

(ii) by striking "section 1162(a)(1)" and inserting "subsection (a)(1)".

(b) TERMINOLOGY CORRECTIONS.—Section 1886(E)(C)(3)(iii) (42 U.S.C. 1395cc(E)(C)(3)(iii)), as amended by section 521 of BIPA, is amended—

(A) in clause (i), by striking "policy" and inserting "determination"; and

(B) in clause (ii), by striking "medical review policies" and inserting "coverage determinations".

"(2) Section 1886(f)(2)(C) (42 U.S.C. 1395cc-

22(a)(1)), by striking "policy" and "policy" and inserting "determination" each place it appears and "determination", respectively.

(c) REFERENCE CORRECTIONS.—Section 1886(f)(4) (42 U.S.C. 1395w(f)(4)), as added by section 521 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking "subclause (i), (ii), or (iii)"); and

(2) in subparagraph (B), by striking "subclause (i)(IV)" and "clause (i)(IV)" and inserting "subparagraph (A)(iii)"); and

(3) in subparagraph (C), by striking "clause (i)", "subclause (IV)", and "subparagraph (A)(iii)", and inserting "subparagraph (A)(iii)", "clause (iv)" and "paragraph (3)(A)", respectively each place it appears.

(d) OTHER CONFORMING AMENDMENTS.—As if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(b) EFFECTIVE DATE.—Except as otherwise provided, the amendments by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PERIOD AT THE END.

The first sentence of section 1128C(3)(B) (42 U.S.C. 1395u(b)(6)(B)) is amended to read as follows: "Subject to paragraph (G), in the case of an exclusion under section 1128C(3)(B), the minimum period of exclusion shall be not less than five years, except that, upon a showing that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or otherwise, the Secretary may waive the minimum period of exclusion.".

SEC. 950. OTHER PROVISIONS.

(a) GAOL REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor for Medicare payments for services under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under section 188E of such title for the succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(b) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of
the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act and the extent to which the rates paid by Medicare are sufficient to ensure the quality of care provided to Medicare beneficiaries. Such report shall include a discussion of the impact of the Medicare payment levels on the ability of Medicare beneficiaries to access necessary care, and the effect of such levels on the financial stability of providers and the economic viability of the Medicare program.

SEC. 1001. IMPORTATION OF PRESCRIPTION DRUGS

(a) In General.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 384 and inserting the following:

"SEC. 384. IMPORTATION OF PRESCRIPTION DRUGS.

'(a) Definitions.—In this section:

'(1) IMPORTER.—The term 'importer' means a person that imports other than a pharmacist or wholesaler.

'(2) PHARMACIST.—The term 'pharmacist' means a person licensed to practice pharmacy, including the dispensing and selling of prescription drugs.

'(3) PRESCRIPTION DRUG.—The term 'prescription drug' means any drug that is prescribed by a physician for a patient and dispensed by a pharmacist or wholesaler, or otherwise used by a patient under the order of a physician for the treatment of any disease or condition of the human body.

'(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

'(5) WHOLESALER.—

'(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 333(a)(2)(A).

'(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 301(d)(1).

'(B) Reporting.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

'(c) LIMITATION.—The regulations under subsection (b) shall—

'(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

'(2) require that an importer of a prescription drug under the regulations comply with subsections (d), (e), and (f); and

'(3) contain such additional provisions as the Secretary determines is necessary to ensure the quality and safety of prescription drugs imported under the regulations.

'(d) INFORMATION AND RECORDS.—

'(1) IN GENERAL.—The regulations under subsection (b) shall require the following information and documentation to be submitted to the Secretary:

'(A) The name and quantity of the active ingredient of the prescription drug.

'(B) A description of the dosage form of the prescription drug.

'(C) The date on which the prescription drug was shipped.

'(D) The quantity of the prescription drug that is shipped.

'(E) The point of origin and destination of the prescription drug.

'(F) The price paid by the importer for the prescription drug.

'(G) Documentation from the foreign seller specifying—

'(I) the original source of the prescription drug; and

'(II) the quantity of each lot of the prescription drug imported or offered for importation otherwise complying with this Act; and

'(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug at a qualified laboratory.

'(I) The name, address, telephone number, and professional license number (if any) of the importer.

'(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

'(II) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

'(III) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

'(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

'(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

'(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

'(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

'(I) is approved for marketing in the United States; and

'(II) meets all labeling requirements under this Act.

'(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

'(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

'(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

'(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

'(2) TESTING.—The regulations under subsection (b) shall require—

'(I) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory.

'(2) if the tests are conducted by the importer—

'(A) that information needed to—

'(i) authenticate the prescription drug being tested; and

'(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act; and

'(B) to otherwise comply with this Act and with such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

'(P) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

'(q) RESTRICTION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

'(s) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an approved written authorization to the importer to use, at no cost, the approved labeling for the prescription drug.
(i) **Prohibition of Discrimination.**

(i) **In general.**—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or other person that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

(ii) **Discrimination.**—For the purposes of paragraph (i), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or does any other measure, that has the effect of—

(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States in accordance with this section.

(j) **Charitable Contributions.**—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug or device that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliated organizations) or to a government of a foreign country.

(k) **Waiver Authority for Importation by Individuals.**

(1) **Declarations.**—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) **Waiver Authority.**

(A) **In general.**—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device under the regulations as the Secretary determines to be necessary to public health and safety.

(B) **In general.**—If, after the date that is 18 months after the effective date of the regulations under subsection (b), a prescription drug or device is imported under subsection (b) and the Secretary makes a certification described in subparagraph (A)(vii)(IV) shall include in the findings of the study under subparagraph (A).

(C) **By the Comptroller General.**

(1) **Study.**—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

(2) **Report.**—Not later than 18 months after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

(m) **Construction.**—Nothing in this section limits the authority of the Secretary to regulate the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

(n) **Effectiveness of Section.**

(1) **In general.**—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date of the regulations under subsection (b), the Secretary submits to Congress a report describing the findings of the study under subparagraph (A).

(2) **Procedure.**—The Secretary shall submit a certification under paragraph (1) only if the Secretary submits to Congress a report describing the findings of the study under subparagraph (A).

(3) **Drugs imported from Canada.**

(1) **In general.**—In the case of a drug that is manufactured in Canada and is imported under subsection (b), the Secretary shall, in accordance with the findings of the study required under subparagraph (C), adjust the number of shipments under the regulations as the Secretary determines to be necessary to public health and safety.
whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) **Recipients of notice.**—An applicant required under this subparagraph to give notice shall give notice to—

(1) each owner of the patent that is the subject of the certification or (a representative of the owner designated to receive such a notice); and

(2) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) **Contents of notice.**—A notice required under this subparagraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(b) **Timing of notice.**—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(c) **Recipients of notice.**—An applicant required under this paragraph to give notice shall give notice to—

(1) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(2) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(d) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(i) **Declaratory judgment absent infringement.**—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a civil action seeking a declaratory judgment on the validity or infringement of the drug, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent.

(ii) **If the certification is in an amendment or supplement to the application.**—If the certification is in an amendment or supplement to the application, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent.

(iii) **If the certification is in the application.**—If the certification is in the application, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent.

(ii) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(iii) **Recipients of notice.**—An applicant required under this paragraph to give notice shall give notice to—

(a) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(1) **In general.**—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent brings a civil action seeking a declaratory judgment on the validity or infringement of the drug, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent.

(2) **Contents of notice.**—A notice required under this paragraph shall—

(a) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(b) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(A) **Timing of notice.**—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(B) **Recipients of notice.**—An applicant required under this paragraph to give notice shall give notice to—

(1) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(2) the holder of the approved application under subsection (b) for the drug that is claimed by the patent (or a representative of the holder designated to receive such a notice).

(C) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(ii) **If the certification is in an amendment or supplement to the application.**—If the certification is in an amendment or supplement to the application, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iii) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(B) **Timing of notice.**—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) **Recipients of notice.**—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(iii) **If the certification is in the application.**—If the certification is in the application, the approving authority shall give notice to—

(a) each owner of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1)(A)(iv); and

(b) the holder of the approved application under subsection (b) for the drug that is claimed by the patent.

(iv) **Contents of notice.**—A notice required under this paragraph shall—

(1) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(2) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.
"(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent is that of the subject of the certification is invalid or not infringed.

(ii) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(2)(A) of title 35, United States Code;";

(iv) in clause (iii), by striking "on the date of such court decision," and inserting "as provided in clause (I), or; and

(v) by inserting after clause (iii), the following:

"(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent infringement and patent validity, and if that court determines that such patent has been infringed, the approval shall be made effective as provided in clause (iii); and

(iii) in the third sentence, by striking "paragraph (3)(B)" and inserting "subsection (B)(3)(C) by redesigning subparagraph (D) as subparagraph (E); and

(D) by inserting after subparagraph (C) the following:

"(ii) ATTAINMENT OF PATENT CERTAINTY.—

(I) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If an owner of the patent under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under subsection (b)(3) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that owner or holder was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

(II) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or use of which is claimed by the patent brings a civil action against the applicant for infringement of a patent or a use of which is claimed by the patent or a use of which is covered by any approved or pending application containing a certification described in paragraph (2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the failure of the owner of the patent to bring an action for infringement of a patent that is the subject of the certification before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or 2(b) is received shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the court of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.

(II) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—The amendments made by subsections (a)(1) and (b)(1) apply with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is pending on or after the date of enactment of this Act regardless of the date on which the proceeding was commenced or is commenced.

(III) EFFECTIVE DATE OF APPROVAL.—

(A) IN GENERAL.—The term "180-day exclusivity period" means—

(aa) the earlier of the date that is—

(1) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(1) or (BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under paragraph (4) in at least 1 of the following has occurred:

(1) the approval has been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (2) (A)(i), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under paragraphs (2) or (5); or

(2) the approval of the application of the first applicant has been withdrawn under section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary under clause (ii) of paragraph (2)(A), but cannot receive effective approval and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(II) EFFECTIVENESS OF APPLICATION.—

(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under paragraphs (2) or (5); or

(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary under clause (ii) of paragraph (2)(A), but cannot receive effective approval and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(II) EFFECTIVENESS OF APPLICATION.—

(AA) IN GENERAL.—The term "180-day exclusivity period" means—

(aa) the earlier of the date that is—

(1) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(1) or (BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under paragraph (4) in at least 1 of the following has occurred:

(1) the approval has been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (2) (A)(i), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under paragraphs (2) or (5); or

(2) the approval of the application of the first applicant has been withdrawn under section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary under clause (ii) of paragraph (2)(A), but cannot receive effective approval and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(II) EFFECTIVENESS OF APPLICATION.—

(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under paragraphs (2) or (5); or

(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary under clause (ii) of paragraph (2)(A), but cannot receive effective approval and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(II) EFFECTIVENESS OF APPLICATION.—

(AA) IN GENERAL.—The term "180-day exclusivity period" means—

(aa) the earlier of the date that is—

(1) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(1) or (BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under paragraph (4) in at least 1 of the following has occurred:

(1) the approval has been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (2) (A)(i), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under paragraphs (2) or (5); or

(2) the approval of the application of the first applicant has been withdrawn under section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary under clause (ii) of paragraph (2)(A), but cannot receive effective approval and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.
to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

"(IV) FAILURE TO OBTAIN TENATIVE APPROVAL. — If the application fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change or reexamination of the requirements for approval of the application imposed after the date on which the application is filed.

"(V) AGREEMENT WITH ANOTHER APPLICANT. — The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder or assignee of the listed drug, or the owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 15 U.S.C. 24 except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

"(VI) EXPIRATION OF ALL PATENTS. — All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

"(VII) FORFEITURE. — The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

"(VIII) SUBSEQUENT APPLICANT. — If all first applicants forfeit the 180-day exclusivity period under the antitrust laws, then—

1. approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

2. no applicant shall be eligible for a 180-day exclusivity period.

(b) EFFECTIVE DATE.—

(1) GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) is effective with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) was made before the date of enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(F)(iv) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(F)(iv) of that Act without regard to whether the first certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act.

(3) DECISION OF A COURT WHEN THE 180-DAY EXCLUSIVITY PERIOD HAS NOT BEEN TriggerED. — With respect to an application filed before, on, or after the date of enactment of this Act for a listed drug for which a certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act and for which neither of the events described in subclause (I) or (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on the date of enactment of this Act) has occurred on or before the date of enactment of this Act, the term "decision of a court" as used in clause (iv) of section 505(j)(2)(A)(vii)(IV) of that Act means the final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

SEC. 1104. BIOAVAILABILITY AND BIOEQUIVALENCE.

(a) In General.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

1. by striking subparagraph (A) and inserting the following:

"(A) the term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

2. by adding at the end the following:

"(B) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect."

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter the standard under section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1105. REMEDIES FOR INFRINGEMENT.

Section 357 of title 35, United States Code, as amended by adding at the end the following:

"(j) CONCLUSION.—In making a determination as to whether an infringement has occurred under section 505(j)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), the court shall consider whether information on the patent was required to be filed but was not, the court may refuse to award treble damages under section 284.

SEC. 1106. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

1. in subsections (b)(2)(A)(i) and (c)(1)(D)(ii), by striking "[(i)(5)(D)] each place it appears and inserting "[(i)(5)(F)]"

2. in subsections (b)(1)(A)(ii) and (b)(1)(C)(ii), by striking "[(i)(5)(D)] each place it appears and inserting "[(i)(5)(F)]"

3. in subsections (c) and (l), by striking "[(i)(5)(D)] each place it appears and inserting "[(i)(5)(F)]"

The SPEAKER pro tempore. Pursuant to House Resolution 299, the gentleman from New York (Mr. RANGEL) and the gentleman from Louisiana (Mr. TAUZIN) each will control 30 minutes.

Mr. TAUZIN. Mr. Speaker, I yield 15 minutes to the gentleman from California (Mr. THOMAS) or his designee, and ask unanimous consent that he be permitted to further allocate that time.

Mr. RANGEL. Mr. Speaker, I yield 15 minutes to the gentleman from Michigan (Mr. DINGELL) and ask unanimous consent that he be permitted to further allocate that time.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New York?

There was no objection.

The SPEAKER pro tempore. The gentleman from New York (Mr. RANGEL) is recognized for 15 minutes.

Mr. RANGEL. Mr. Speaker, I yield myself such time as I may consume.

The SPEAKER pro tempore. The statement made by the gentleman from Louisiana (Mr. TAUZIN) that we all are concerned about our older citizens and those that are to follow, and certainly we all have to appreciate the fact that all of our time has been based on someone else’s shoulders, someone else who made the sacrifice, and I am very proud to share the responsibility of this bill with the gentleman from Michigan (Mr. DINGELL), who has dedicated his entire life, and his dad before him, in making certain that he and those of us who support him and what he believes in improves the quality of life not only of the seniors today. It took us a long time to get where we are where people feel some degree of comfort that the Federal Government will be there for them, whether it is Social Security, whether it is Medicaid, whether it is Medicare. It has been nice to have Government, this wonderful government which gave me the GI bill, this government which allowed older citizens to have some degree of pride in having Social Security to cushion themselves from poverty, and this government that provided health care for the very poor, and under Medicare we had hoped that we would have provided prescription drugs for them.

I do not know when this animosity came against government, because we felt we had to starve these programs which some of us have been so proud of. Somebody asked how do you pay for your bill? This is a strange thing to ask, especially when the chairman of the Committee on the Budget for and ask? Can we have the numbers over there. He started with a $5.6 trillion surplus, and with magic converted it to a $3.4 trillion deficit. He can take $9 trillion and find the way to cut the cuts. Even tonight, some $173 billion, $100 billion just found last night, and we will get $400 billion from what they have allocated, but we think that it takes twice that much.

That asking to do, is that something that we have to go to the Committee on the Budget for and ask? Can you sprinkle your magic powder on us and make it possible for the older people to have the same services? Is it asking too much to treat them, not that they are wealthy in dollars and cents, but they are wealthy in terms of the investment they made in this country to make it possible for the multi-billions and the tens of billions to get the tax breaks that they are getting, and it seems to me since compassion is not there, that maybe we can look at it as a cost savings vehicle.

How many senior citizens will not have to go to the hospitals which are so expensive, how much of a part of our health expenses is a part of the institutions which our seniors are forced to go
into? If you have to make a decision and you are in doubt, why not make the doubt in favor of the senior citizens? Everything that is missing in the Republican bill that is good, we put in our bill to make certain that it is better.

One thing that we are saying is this, do not hate the government until you do not have any need for it. And seniors when they read the difference of the bills, and you bet your life they can read, they may be old but they are not stupid. I asked my old church lady to pick up the daily newspapers, and if they do not go to the pharmaceutical corporations but rather go to the local drugstore, they will find out in short order who is their best friend.

Do not knock the government. It is not as bad as some Members think. Give the people an opportunity so that we can say citizens, we appreciate all that you have done for us, and we in the Congress believe that the least we can do, you grow older is to ease your pain and, more important, the fear you have that once you go to the doctor that at least you will be able to get the drugs that are prescribed for your illness.

Mr. Speaker, we do not have to challenge each other's integrity, but I tell Members this, that there are Members on the other side of the aisle that hold Social Security in utter contempt. There are Members who talk about Medicare as though the communists created the package, and theyresented it when it started, and they think it is worse than ever today.

What I am saying is let us do what they tell doctors to do, and do no harm. Let us leave here saying that at least on this day there was a substitute, they did not have to do it the way the majority would want.

Mr. Speaker, I yield the balance of my time to the gentleman from California (Mr. Stark), the ranking member of the Subcommittee on Health, and I ask unanimous consent that he may further allocate that time.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New York?

There was no objection.

Mr. WILSON of South Carolina asked and was given permission to speak out of order and to revise and extend his remarks.

Mr. WILSON of South Carolina. Mr. Speaker, it is with great sadness tonight that I announce that Senator Strom Thurmond passed away at 9:45. I was a former staff member of Senator Thurmond, my wife was a staff person for Senator Thurmond, and our three sons have been pages with his office.

With the death of Strom Thurmond, South Carolina has lost its greatest statesman of the 20th century, just as J ohn C. Calhoun was the greatest statesman of the 19th century. Strom Thurmond will never be replaced in the countless hearts of those who loved and respected him.

The entire Wilson family mourns this profound loss and we extend our sympathy to the Thurmond family.

Senator Strom Thurmond will endure as the leading example of a public servant due to his love and devotion to all the people of South Carolina regardless of status, race, politics or region.

He was our living legend. Strom's life was dedicated to achieving peace through strength, as shown by his military service in liberating Europe from Nazi fascists, his tireless work in fighting for the defense of our country in the Congress which ultimately led to the defeat of Soviet communism.

He pioneered the development of the South Carolina Republican Party from effective nonexistence in the 1960s to majority status by the end of the century. He has been a role model of service to South Carolina's young people and our family has had three generations on his staff: my wife's two uncles were staff attorneys, my wife and I were interns, and our three oldest sons were pages. A distinguished highlight for our family was to host Senator Thurmond on the last Sunday before his last election in 1996 at the First Presbyterian Church in Columbia.

The legacy of Strom Thurmond will always be felt in South Carolina because of his steadfast integrity and the meaningful thoughtful constituent service. He was my personal hero, and I will miss him dearly.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

Let me join in expressing the sorrow of the folks in Louisiana for your loss in South Carolina. We will pray for his soul.

Mr. Speaker, the Democratic substitute in this debate can be summed up rather easily. According to CBO, it would spend $130 billion dollars. It busts the budget. Therefore, it is on the floor with a budget waiver. It at the same time excludes and does not contain any of the reforms that the base bill includes, that are designed to save Medicare from failure, from insolvency. I am not predicting Medicare's failure or insolvency. CBO is, CRS is. Everyone who has estimated the strength of our Medicare system predicts very soon, in our lifetimes, it will go insolvent. None of the reforms that are designed to save Medicare from insolvency are here. In fact, the Democratic substitute piles on a trillion dollars worth of expenses to the Medicare system with no reforms to make sure the system is saved.

When I mentioned earlier that you ought to test the credibility of arguments on this floor by what is said and what is fact and what is of record, let me take you back to the statements of the distinguished gentleman from California when it voted on its base bill because CBO said it might mean that as much as 30 percent or so of employees might drop their retiree coverage under the base bill in favor of the plans we offer. CBO estimated the Democratic substitute, too, on that point.

How credible is an argument against the base bill that claims about a potential 30 percent loss of employer coverage when CBO estimates that 100 percent of employers would lose retiree coverage under the Democratic substitute? That all taxpayer dollars will be used to substitute private dollars? And the Medicare system, already crushed and about to go into insolvent, will have to assume all that responsibility, too? If you really believe in Medicare, why would you burden it so? Why would you eliminate private coverage in America, as CBO estimates would happen under the Democratic substitute?

This substitute busts our budget. It purports to provide more drug coverage than the base bill but no reforms, it does not save Medicare; and on top of that it virtually eliminates private retiree coverage in America. Why would we want to go that direction? We rejected that direction during the Clinton years when Mrs. CLINTON presented us with one-size-fits-all health care for all Americans. We recognized then that if you do not have the competitive clause in America in health care, just as we do with so many other services, that things go bad in this country and that sooner or later the crushing weight of benefits added upon benefits added upon benefits means the working people of America have to pay more and more and more taxes. In fact, it is estimated that within 70 years, if we do not begin today making decisions like we ask the House to make, entitlements in America will eat up every tax dollar paid into the Treasury by every citizen in America, and we will have no money for any other function in this country. That is where this substitute takes us, and that is why we need to reject it.

Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

Mr. DINGELL asked and was given permission to revise and extend his remarks.

Mr. DINGELL. My dear friends and colleagues, I lay before you the Republican plan. I ask you to look at it with a straight face, because it is inexplicable, and I cannot explain it to you with a straight face. It is an amendment which was offered by my dear friend, the gentleman from New York (Mr. RANGEL), on behalf of him and me, does the following things: it gives and sets forth a very clear set of benefits. Senior citizens pay $25 a month; they get 80 percent of drug costs from government after a $100 deductible. This is what you get if you get the Republican plan. But that is not what the worst you get. If you are a senior citizen, you fall into a drug trap. After you get $2,000 in drugs that you get under the plan, all of a sudden your payments by the government stop; you have to keep on paying premiums, but you get no benefit
until you have got $5,100. They are going to privatize your Medicare in the year 2010. That is pretty bad.

But it is followed by other things: massive subsidies to the insurance companies which commence in 2 years, in 2002. Not all. We are not going to guarantee as to what it costs you in terms of what you have to pay in the way of premiums, no assurance that you will get any particular level of benefits. The only person who is going to cut this fat hog out of this deal are those good-hearted, flinty-hearted, cold-hearted folk in the insurance business who are going to all of a sudden get a key to the United States Treasury, the right to collect any amount of money they want and to sicken the Secretary of HHS any old way they are minded and to walk home and to pay the money perhaps to the senior citizens but possibly to their shareholders or in dividends or perhaps to pay it in salaries or in bonuses to their corporate officers. That is what you get under the Republican plan. And privatization of Social Security as you know it today.

The Republicans have said that they intend to privatize Social Security. Well, this is what is happening here. The Democratic plan compels the drug houses to negotiate with the Federal Government and the Secretary. The Republicans preclude him by absolutely prohibiting him from negotiating. We do not tolerate under the Democratic plan the Republican opportunity to privatize Medicare. And just wait till your senior citizens find out what you are doing to them with privatization and substituting in lieu of this the kind of plan that you talk about they will not have public education the way we know it today. They will not have the roads and bridges that a strong economy depends on. They will not be able to defend this Nation in a world that is going to be far more dangerous than the one we have known. This is utterly irresponsible. It is so irresponsible that when the other body proposed this plan in the Senate the last session of Congress, they could not write a budget resolution because they did not know how to handle the extraordinary debt that this creates in the decades ahead.

I urge my colleagues to think that something that looks pretty for your seniors. In fact, it will be terrible for their health.

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. GREENWOOD), the chairman of the Oversight and Investigations Subcommittee of the Committee on Energy and Commerce.

Mr. GREENWOOD. Mr. Speaker, I thank the chairman of the committee for yielding me this time.

The gentleman from Michigan (Mr. DINGELL) and others have presented a chart earlier that purported to show that somehow our plan was more complicated. It is a complicated issue to provide prescription drug benefits to millions of Americans who have never had them.

Let me show another chart that describes our plan and it is not complicated at all. Today a senior citizen walks into a drugstore and wants to buy Lopressor, 100 milligrams. She has to pay, for 30 tabs, $45.99 right out of her pocket. Under our bill the price first comes down because the group purchase will bring it down to $36.79 and then what does she pay? She pays $7.36 and if she is low income she pays $5. That is a big difference from $46.

We have introduced a substitute. Unlike your bill, ours has specific benefits. Your bill, I would remind the gentlewoman from Connecticut, has no benefit in it. It is all estimates. It is all examples. There is no benefit in your bill and indeed in our substitute there is. You have heard it. It is simple. It is $25 a month, 20 percent coinsurance, no gaps; and we pay out of pocket after $2,000.

Yes, you will say it costs a lot of money. The gentlewoman from Connecticut forgets about the $5.6 trillion surplus that Bush had when he came into office and which he squandered on tax cuts in the meantime. But we do have an income transfer as we have been accused of. It is very simple. You can look at it this way. You have given $800 billion to 10,000 of the richest families each year when you did away with the inheritance tax. No question about it. That is what it costs. Those are the Democratic priorities. We would give $800 billion as an alternative and give it to what will be in a short 10 years 100 million seniors. What you have given away to the richest seniors in this country and more than paid for a drug benefit of the magnitude that we offer, a standard Medicare drug benefit, and I suggest that that is a transfer worth making and that that defines the difference between us.
Let us look at Lipitor. An awful lot of Americans take Lipitor every day to keep their cholesterol down. It does. It costs $108.65 today because for 40 years the Democrats did not do anything about prescription drugs and for 8 years President Clinton did not do anything about prescription drugs, but under our plan Lipitor goes down to $86.92 because of our purchasing power, but the beneficiary pays $13.00 for a month’s supply and if they are a poor senior citizen, $5, $5, down from $86.28.

Zoloft, 100 milligrams, 30 tabs for a month, it is an antidepressant. A lot of elderly suffer from depression, unfortunately, at their age in part because they do not have good health care. We bring the price down to $63.17. The beneficiary pays $12.63 a month and, if she is poor, then it is free.

This chart is pretty straightforward and pretty simple. This demonstrates what happens when good-minded people do very hard work with very smart people, employing very good ideas. We get the job done for the elderly, a job that I am sorry to the gentleman from California (Mr. Stark), I am sorry to the gentleman from Michigan (Mr. Dingell). They have been here for a long time and they have done nothing. A lot of talk tonight. A lot of good talk, a lot of bogeyman talk, a lot of scare-the-seniors talk tonight, but we will get this done. It will be very simple. It will be very straightforward. The seniors will love it, and as a measure of that you are all going to be voting for it.

Mr. Dingell. Mr. Speaker, I yield myself 15 seconds.

I hope my colleagues look at that chart because it has the same factual value as Alice in Wonderland. There is no requirement that any of those drugs be made available. There is no requirement that they be made available at any particular price or that they have to be made available under the plan at any particular price because of cost sharing with the insurance. Mr. Speaker, I yield 2½ minutes to the distinguished gentleman from California (Mr. Waxman).

Mr. Waxman. Mr. Speaker, today the House should be considering a Medicare prescription drug benefit for all America’s seniors and disabled citizens that would be a benefit that is certain, a benefit that is affordable, and a benefit that helps Medicare beneficiaries with all of their drugs. It should not have large gaps in coverage as the Republican bill does. It should not let private insurance companies charge whatever premium they want and cover whatever drugs they want as the Republican bill does. It should be available in every part of the country, not only in areas where private insurers decide they can make a profit, and it should not cost seniors more if they live in Iowa instead of Virginia or California. Instead of Rhode Island. Most importantly, it should be a part of the Medicare program, just as dependable as the rest of the Medicare is for seniors and disabled people today.

The Republican bill fails all of these tests. It is on the one hand and then takes them away when we read the fine print. It claims to give special help to America’s low-income seniors so that they can afford to pay for the prescription drug program, but then it makes seniors subject to a detailed and invasive assets test before they can get help.

If they have over $6,000 in the bank, they do not get any help. When we figure out what they have got if they have a $4,500 car, and the value of their burial plot if it exceeds $1,500. So instead of making sure people of very modest income who need help to get in, they get the fine print eliminating a lot of these people who should be helped, and it makes all of them go through a demeaning and complex process to prove they have few assets.

All this to get help with their drug expenses. This is just wrong. Instead of spending the public’s money to get the best possible drug benefit, this Republican bill spends our dollars to bribe insurance companies to sell a drug plan. It pays for profits for the insurance companies instead of the bills for our seniors.

What we should be doing is using the purchasing power of America’s seniors, 40 million of them, to get good prices on their drugs as they do in Canada and get good coverage. That is what the Democratic substitute does. I urge my colleagues to vote for the Democratic substitute and against the Republican bill.

Mrs. Johnson of Connecticut. Mr. Speaker, I yield 2 minutes to the gentleman from Iowa (Mr. Nussle), a member of the Committee on Ways and Means, who understands that spending money to provide a decent drug benefit for seniors is not wasting money.

Mr. Nussle. Mr. Speaker, I thank the gentlewoman for yielding me this time.

I would like to know where the new Democrat budget hawks are tonight, those new birds who seem to have flown the coop, who have spent the last many months here on the floor talking about the debt tax, something that does not exist. It’s a lot of ink about it. All sorts of national debt charts have been coming across the floor. In fact, they even one day used the pages, these young high school students, to demonstrate the national debt. But where are they tonight? Where are they when we read the letter from the Congressional Budget Office that says that their so-called substitute would add $1 trillion to the deficit? Where are they? They are up in Indiana, in a hearing about the deficit all of a sudden. In fact, what we heard about is that tax cuts have caused all of the problems.

In fact, one gentleman even had the audacity to stand up and act as though Washington hands money out at the expense of the people. Tax relief, my friends, is money left in the pockets of people that they earned. We do not hand money out. Money comes from them. And if you are going to waste it on a $1 trillion program, that not only does not fit within the budget that controls tonight but did not even fit within your substitute budget of just 4 months ago.

In fact, if we add the Democrat budget together with the budget that Congress on Tuesday, you must not only the Republican budget, but you must budget combined. That takes a lot of work, to be able to bust both budgets and add $1 trillion to the deficit and have all of these things. The only way one may today that hawks whom we cannot find tonight.

It is interesting. Boy, we heard a lot from them all year long, nickeling and diming and worrying about all of that. But when you come to the floor with $1 trillion to the deficit and have all of the employers are going to drop their coverage for retirees, 100 percent are going to drop their coverage, and you have the audacity to present that kind of substitute that busts both budgets, do not come here any more this year and talk about the deficit.

Mr. Stark. Mr. Speaker, I yield myself 30 seconds.

I have the same letter, and it says nothing about employers dropping coverage.

Mr. Speaker, I yield 2 minutes to the gentleman from Washington (Mr. McDermott), a member of the Committee on Ways and Means, who understands that spending money to provide a decent drug benefit for seniors is not wasting money.

Mr. McDermott. Mr. Speaker, Members of the House and those listening to this, I think you ought to take some of the paper right here and write this down. The premium is $25. The deductible is $100 a year. The coinsurance means you pay 20 percent, the government pays 80 percent for your drugs, and there is a cap on how much you can spend out of pocket, $2,000. That is written into our bill.

In contrast, we have this magic pill that has been given to us where the other side says trust us. Remember, these are the people who told us that they were weighing the destruction in Iraq. They were right there. They were going to be delivered in 45 minutes. And, in fact, the President of the United States stood right here and
said, Mr. Speaker, that he believed that they had tried to buy uranium from Niger. It was known that that was a lie. It was known. So now they come out here with this drug bill and they say listen, we will be about $35 and maybe you will get this and maybe you will understand that, but nothing is written down. I want the people to remember those four things.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. Hastings of Washington). The Chair reminds the Member not to make personal remarks regarding the President of the United States.

Mr. TAUSIN. Mr. Speaker, it is almost like Minister of Information Baghdad Bob just arrived here.

Mr. Speaker, I yield myself 2 minutes.

PARLIAMENTARY INQUIRY

Mr. MCDERMOTT. Mr. Speaker, Parliamentary inquiry.

The SPEAKER pro tempore. The gentleman from Washington (Mr. McDermott) is not in order since the gentleman from Louisiana (Mr. Tauzin) has the time and such a point may not challenge debate.

Mr. TAUSIN. Mr. Speaker, I want to illustrate one of the real inadequacies of the Democratic substitute. In the main bill we reformed something called average wholesale price. I hope everyone knows what that is. I am going to illustrate it for you tonight. Under average wholesale price systems built into Medicare by the Democratic Party all these years, this is what happens. A person goes in for cancer therapy, a senior citizen, and the doctor needs a drug that costs $10, so the doctor buys a chemotherapy drug for $10. The patient ought to have to pay $2 under that, 20 percent co-pay under law. But that is not what happens. Under the average wholesale price system devised by Democratic administrations in the past under Medicare, this is what happens. The government has a phony average wholesale price posted. It might be $200 for that drug that only costs the doctor $10, and the poor patient has to put up 20 percent, not of the $10 but 20 percent of the $200. The patient puts up $40 for a drug that only costs the doctor $10 when the patient should have put up $2. That is called the average wholesale price system. It is rotten. It stinks. Our bill gets rid of it.

Mr. Speaker, I yield myself 2 1/2 minutes to the distinguished gentleman from New Jersey (Mr. Pallone).

Mr. PALLONE. Mr. Speaker, the only thing that stinks here is the Republican bill, and it stinks for a lot of reasons.

First of all, because it is not going to give the seniors any benefit. They are not going to have really any drug benefit whatsoever. It is going to force them into an HMO. They will not have any choice of doctors. And fundamentally, in the end what the Republican bill does is set up a voucher system so we do not even have traditional Medicare. I am sick and tired of hearing my Republican colleagues on the other side criticize traditional Medicare. Medicare is a good program. Do not tell me that Medicare is broke or Medicare needs to be fixed. And I say to the gentlewoman from Connecticut, do not insult me and say the Democrats are irresponsible, the Democrats are putting us in debt. The Republicans are the ones that are putting us in debt, because you are borrowing from the trust fund so there is no money left in it because you want to kill Medicare. That is what you are all about.

These gentlemen over here, these Democrats who have been here for a long time, they are here tonight because they want to save Medicare. They understand that Medicare can be put on a sustainable prescription drug benefit, so they look at the tried and true system, they look at what we do in part B for our doctor bills, and they say, yes, let us just add a benefit like part B. We will have a low premium. We will have a low deductible. We will pay 80 percent of the cost on the Federal Government. We will have a catastrophic at 2,000. Just add the tried and true program, like we have in part B, and add a drug benefit. We do not need HMOs. We do not need all of these other things that the Republicans come up with.

And then these gentlemen, my colleagues, the gentleman from Michigan (Mr. Dingell) and the gentleman from New York (Mr. Rangel), they say, well, we can pay for this very easily by negotiating the price and giving the Secretary the power to lower the prices. That would cut the program in half. That is what our Democratic leader said. That would cut the cost of the program in half so we would not have to go into debt. We would not have to borrow from the trust fund and make it insolvent, which is what my Republican colleagues have been doing here and do they are proposing.

Mr. Speaker, do not sell out to the HMOs and the insurance companies. That is what you are doing. You are selling out by saying everybody has got to go into an HMO because you are in bed with the insurance companies. You are selling out to the pharmaceutical industry because you want no price reductions, because you are going to get some benefit from the pharmaceutical industry.

And then you come up with: this is complicated. The gentleman from Pennsylvania (Mr. Greenwood) said, oh this is complicated. There is nothing complicated here. It is simple. We have had the program for years. We just add the prescription drug benefit, and we have a negotiated price. It is very simple.

Do not give me this chart. I mean, look at this garbage. How could anyone possibly understand it? I cannot even understand it myself, and you expect my mother or somebody’s grandmother to understand this thing? You are making it complicated. You are destroying Medicare. Do not insult us as Democrats. We have been out there protecting it for years.

Mrs. JOHNSON of Connecticut. Mr. Speaker, it is my pleasure to yield 2 1/2 minutes to the gentleman from Wisconsin (Mr. Ryan), a member of the Committee on Ways and Means.

Mr. RYAN of Wisconsin. Mr. Speaker, I thank the gentlewoman for yielding me this time.

I want to calm down a little bit. There has been a lot of shouting around here, a lot of heated rhetoric, a lot of hyperbole. Let us just look at a couple of facts.

It is a fact that the Medicare actuaries are telling us that Medicare is going insolvent in 13 years. The entire system is going to go under. It is a fact that if we add more money on top of Medicare without doing any reforms, you are going to accelerate the insolvency of Medicare. We can try and speak those facts away, but the fact remains that those are facts.

Now, what this Democrat substitute does is it costs over $1 trillion. It accelerates the bankruptcy of Medicare. The basic assumption in this CBO estimate is that every employer providing private drug coverage for their retirees is going to drop it. And why would they not? Why would they not drop it if the Federal Government is going to pay for it all?
What the facts are is that this plan is going to accelerate the bankruptcy of Medicare.

Now, what are we trying to achieve with the Republican bill? Mr. Speaker, there are parts of this bill that none of us in this hall like very much. But what we are trying to achieve is not only modernizing this program so it works for today’s seniors by giving them cheaper drugs and coverage of drugs, but we are also trying to modernize this program and save it for the baby boomers.

We have 77 million retirees coming in this country starting in 15 years; and if we accelerate the bankruptcy of this program as the Democrats are proposing to do, it is not going to be there for them.

So what we are doing with these market-based reforms and giving seniors more choices? We are giving them the chance that this program will be solvent for the boomers when they retire. That is what people expect out of this country.

The responsible thing is to make it work for today’s seniors, make it modern, make it comprehensive, work on prescription drug prices, work on prescription drug coverage, but give seniors more choices, use competition, use the things that have worked in the past so we can save this program for the baby boomers. That is what the Republican bill does.

Mr. STARK. Mr. Speaker, I yield myself self 30 seconds for a couple of housekeeping things.

In 13 years, the revenues start to decline, but it does not go insolvent for 24 years. And I say to the gentleman from Ohio (Mr. NUSSELE), if he has indeed the same letter that I am aware we have from CBO dated June 26, it says nothing in there about employers turning back Medicare, so he either misspoke or made it up, which, in my State, we call telling a lie. Unless he has a different letter, which I am assured by CBO he does not, then he made it up.

Mr. Speaker, I yield 1 minute to the gentleman from New Jersey (Mr. MENENDEZ).

Mr. MENENDEZ. Mr. Speaker, I rise on behalf of my 84-year-old mother and millions like her across this country. She worked her entire life in the factories of New Jersey. Today she has Alzheimer’s and spends over half of her Social Security check on prescription drugs. If it was not for my sister and me, she would not be able to live with the dignity she deserves.

Now, this Republican package is wrapped in a label that says, “I care,” but when you open it up, it contains nothing more than an empty promise.

Under this Republican plan, which lacks the compassion promised by the President and expected from our doctors, millions of seniors who want to stay in traditional Medicare will have to buy expensive HMOs that would essentially be forced into HMOs and left without the choices they deserve. This bill is the road toward privatizing Medicare.

Republicans just cannot help themselves. Once again, they have chosen corporate interests over human interests. America’s seniors deserve our respect. They have worked too hard, sacrificed too much to be forced to choose between paying their rent, putting food on the table or having access to life-enhancing drugs.

Support the Democratic substitute that has a real prescription drug provision under Medicare.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from California (Mr. CUNNINGHAM), our fighter pilot commander extraordinaire.

Mr. CUNNINGHAM. Mr. Speaker, I had pneumonia about 5 years ago, and I went to pick up the prescription drug and I looked at it. It was $120 bucks. As I picked it up, I sat there and I thought, how does a family with three or four children afford $120 bucks per bottle of Augmentin to help them with the flu? I thought that was a real fact. It is hard.

But Mr. Speaker, I say to the gentleman from Michigan (Mr. DINGELL), does he know the cost of my prescription drug? It cost me $17. Because my wife worked in my school district and she had insurance. That is what we want, is a private-public partnership for those people that cannot afford prescription drugs to help them. Over 1.4 million people in California will have no copay, no cost whatsoever.

But it will help them in our bill.

I think that your bill, with its costs, is devastating in the long run. It will not help.

If Democrats can demonize pharmaceutical companies, then what is left? The government. If you can demonize insurance companies, what is left for health care? Government-controlled health care. We rejected that in 1993 when the then First Lady offered it. I recommend government-controlled health care, and maybe that is the difference in us, because it will drive this country in debt.

I talk to some people from Canada. Do my colleagues know where they go to get their health care? They come down to Buffalo, New York to get it, because it is so bad with their government-controlled health care.

Let us defeat the Democratic substitute and support the primary bill.

Mr. STUPAK. Mr. Speaker, the Republican prescription drug plan is bad for America and even worse for rural America.

Today I sent around a letter to Members explaining exactly why this GOP bill shortchanges rural areas like Northern Michigan, which I represent.

The Rangel-Dingell substitute ensures that rural areas are treated fairly. The Republican plan continues to put citizens in these areas at a huge disadvantage. The Rangel-Dingell bill goes far beyond the meager provisions for rural health care providers included in the GOP bill. Our bill, the Democratic bill, provides over $10 billion in additional relief for rural areas and removing the harmful Medicare privatization provisions that just have not worked in rural America.

Instead of helping seniors with their prescription drug plan, the Republican plan subsidizes private insurance companies. This plan tends to bribe private insurance companies to provide service in rural districts like mine. These insurance companies have come before our Committee on Energy and Commerce and have testified that they will not be providing the service, and the Republican plan just will not work.

If insurance companies do change their minds, there is nothing in this bill that will prevent them from shifting the added costs to our seniors. I had an amendment in the Committee on Energy and Commerce that would have prevented increases in the monthly premiums for those who live in the areas where they live. But unfortunately, it was voted down on a party line vote.

The GOP plan has a huge gap in coverage and does nothing to reduce the inflated prices big drug companies are demanding for prescription drugs. In fact, the Republican plan has a noninterference clause that says the Health and Human Services Secretary will not, will not be allowed to negotiate lower prices for Americans.

The Rangel-Dingell bill will ensure that every senior, regardless of where they live, will be able to obtain the prescription drugs and the quality of health care they require to live a healthy life. This coverage will be provided through Medicare. Democrats are working to strengthen this program, not to do away with it, as the gentleman from California (Mr. THOMAS) called for when he said, and I quote him, “To those who say the GOP bill will end Medicare as we know it, our answer is: We certainly hope so.” Thus, the real motive behind the GOP plan is to do away with Medicare. Democrats proudly stand behind Medicare. Support the Rangel-Dingell substitute.

Mr. JOHNSON of Connecticut. Mr. Speaker, I yield 2 minutes to the gentleman from Arizona (Mr. HAYWORTH), a member of the Committee on Ways and Means.

Mr. HAYWORTH. Mr. Speaker, I thank my friend from Connecticut, and she has visited and knows now that the hour grows late and the debate grows heated and sometimes well-intentioned efforts from some are thrown in the confusion.

Mr. Speaker, I rise to urge this House to reject the Democratic substitute and to vote “yes” for H.R. 1 for reasonable, rational, clear-cut reform of Medicare that will bring Medicare into the 21st century with prescription drug coverage.
Seniors are crying out for help, but their pleas are drowned out by the cash registers humming away at the majority party headquarters, while insurance and pharmaceutical company lobbyists rush to the great Medicare sellout of senior citizens. The irony is, my friends on the left in the trillion dollars travesty section say, do not worry. Let us break the bank. Let the good times roll. Take command and control, put it together with a trillion bucks. No worries. But we know what would happen under that plan. It is a prescription for bankruptcy. America wants a prescription drug program that does not mortgage the future of the working families that my friends purport to support. People of good will can have different opinions, and we certainly have them here. But when the question often comes down to this, when is enough enough? With the left it is never enough.

Reject insanity. Vote for rationality, “yes” to H.R. 1; “no” to the Democratic substitute. The SPEAKER pro tempore (Mr. HASTINGS of Washington). The Chair would remind Members of the time remaining. The gentleman from Louisiana (Mr. TAUZIN) has 4½ minutes remaining and would like to close. The gentleman from California (Mr. STARK) has 3½ minutes remaining and would ask to be next in line to close. The gentleman from Michigan (Mr. UPTON), the chairman of the Subcommittee on Telecommunications and the Internet of the Committee on Energy and Commerce, has 4½ minutes remaining and would be the first to close.

The Chair recognizes the gentleman from California.

Mr. STARK. Mr. Speaker, I yield 1 minute to the gentleman from Ohio (Mr. KUCINICH).

Mr. KUCINICH. Mr. Speaker, everyone in America knows the price of drugs is too high. Seniors know it best. Proponents of H.R. 1 are not representing the seniors of America. They represent the biggest campaign contributors in America, the private health insurance industry led by drug makers.

The Rangel-Dingell substitute will bring down the cost of the drugs. It allows Medicare to buy drugs in bulk and negotiate for lower prices, which the VA already does. Skyrocketing drug costs are not only driving up health care costs, but are causing seniors to make cruel choices between prescriptions and food, prescriptions and clothing. Some seniors are even splitting pills to make prescriptions last.
trillion dollars would provide coverage for those who do not even need it. It sounds like what they accuse Republicans of.

I was really interested to see, when you look at page 12 of the Democrat bill, there is all sorts of things that are interesting. They say we do not provide guaranteed access. We do provide guaranteed access. The government actually steps in when there are not plans available, negotiates down the risk which increases access.

If you look at page 12, what does the Democrat plan do? It says, “The Secretary shall develop procedures to ensure coverage.” That will give you some comfort. I can see why they are not talking about their legislation. I would not either. Vote for the underlying bill. Vote down this substitute that they will not talk about.

Mr. SHAKOWSKY, Mr. Speaker, I yield myself 1½ minutes.

Mr. Speaker, just to straighten out some of the figures, the Republicans do indeed add $26.7 billion for rural providers, $1 billion for rural providers. That is $2.5 billion more, and I would hope that the Republicans are not lying to the seniors.

If you can lie to us because we are used to it. The White House has set the tone for that. But do not lie to the seniors.

There is nothing in your bill. I say to the gentleman from Ohio (Mr. PORTMAN), there is nothing in your bill that guarantees anything, and to say that to the seniors is lying to the seniors.

There is nothing in your bill that guarantees a thing to the seniors and you know it. And if you do not know it, read it again. Otherwise, you are lying to the seniors.

Our bill provides a Medicare benefit which is definable. Yours does not. You do not require any benefits if no insurance company steps up to the plate and there is nothing that requires it. There is not one line in your bill that requires an insurance company to provide anything. So it is all a fantasy. At least we are requiring the government to provide a benefit to the seniors in the same manner they are now familiar, under Medicare with a determined premium, a determined deductible, determined benefits, the same across the country. None of that is available through the Republican bill. To tell the seniors otherwise is lying. You have lied to us tonight and stop lying to the seniors. To support our substitute and vote down the great Republican lie.

Mr. DINGELL, Mr. Speaker, I have an inquiry as to time first before I yield the balance of my time. I believe the gentlewoman from Illinois (Ms. SCHAKOWSKY) did not get the full 2½ minutes that I yielded to her. I would like to know how much time I have left and how much I can properly yield the gentlewoman from Illinois.

The SPEAKER pro tempore. The gentleman from Michigan has 3 minutes remaining.

Mr. DINGELL, Mr. Speaker, I yield 1 minute to the distinguished gentlewoman from Illinois (Ms. SCHAKOWSKY).

Ms. SCHAKOWSKY. Mr. Speaker, I thank the gentleman from Michigan (Mr. DINGELL) for yielding me time.

Again, this is just a warning, a friendly warning to you that if you pass H.R. 1 tonight, you better also go out and get your running shoes because the seniors are too smart to be fooled by your proposal. And you can trash Medicare all you want. You can call it an outdated program, antiquated; but I do not know who you are talking to. I do believe that you love your mothers, but it is obvious to me that you do not call them enough. You do not go to senior centers enough. Not the ones I have gone to in my 5 years as director of the State Council of Senior Citizens. Seniors love their Medicare. The only thing they do not like is that it does not cover prescription drugs. And that is why if you are smart or out of shape not to be chased by seniors, you will vote for the Rangel-Dingell substitute.

The Democratic substitute is what seniors have been asking for and what every politician has been promising them, an understandable, defined, dependable Medicare prescription drug benefit. It has all the features of Medicare that our seniors know and love, a set premium, no copayments. Vote for the substitute or start running.

Mrs. JOHNSON of Connecticut. Mr. Speaker, I yield 1½ minutes to the gentlewoman from Virginia (Mr. TOM DAVIS).

Mr. TOM DAVIS of Virginia. Mr. Speaker, I would like to engage in a colloquy with my colleague.

Can she confirm that the language in H.R. 1 includes plans under the Federal Employee Retirement Plan as an employment base plan?

Ms. JOHNSON of Connecticut. Mr. Speaker, will the gentleman yield?

Mr. TOM DAVIS of Virginia. I yield to the gentlewoman from Connecticut.

Mrs. JOHNSON of Connecticut. Mr. Speaker, yes, that is correct.

Mr. TOM DAVIS of Virginia. This will allow OPM to take advantage of the subsidies in the bill just as other employees and unions will.

Mrs. JOHNSON of Connecticut. That is correct.

Mr. TOM DAVIS of Virginia. Mr. Speaker, I appreciate the gentlewoman's and the chairman's willingness to work with us on this issue. I think that allowing the subsidies H.R. 1 provides for will result in lower premiums and improved benefits for all FEHBP enrollees.

Mrs. JOHNSON of Connecticut. I thank the gentleman, and I look forward to working with the gentlewoman on this issue as the bill moves to conference.

Mr. TOM DAVIS of Virginia. Mr. Speaker, as I said, I appreciate the willingness of the gentlewoman to clarify that.

I have another concern, that Federal employees are often treated differently from current Federal employees in ways that are not always equitable. Retirees are different from current Federal employees. For example, current Federal employees need to pay their health insurance premiums from pre-tax dollars. Federal retirees are not.

FEHBP currently does not provide different benefits for retirees and current employees. One is simply a member of FEHBP. I believe it is important that this dynamic remain once a Medicare prescription drug benefit is put into place, whichever plan passes.

As chairman of the Committee on Government Reform, I look at this from an employer's perspective. We do not want private employers to drop the prescription drug coverage they provide for their retirees. H.R. 1 provides incentives so that they will not do so, but we as the Federal Government have to lead by example.

I have introduced legislation that simply states that Federal retirees will continue to be treated on par with current Federal employees when it comes to prescription benefits. I regret we were unable to include this language in H.R. 1, but I am grateful to have the commitment of the Speaker and the majority leader to bring this bill to the floor as soon as we return from recess.

Mr. TAUZIN. Mr. Speaker, may I inquire on how many minutes is left for each one of the four who have allocated time?

The SPEAKER pro tempore (Mr. HASTINGS of Washington). The gentleman from Louisiana (Mr. TAUZIN) has 2 minutes remaining and the right to close. The gentleman from California (Mr. STARK) has 1 minute remaining and would be next to close. The gentlewoman from Connecticut (Mrs. JOHNSON) has 2½ minutes remaining and the gentleman from Michigan (Mr. DINGELL) has 2 minutes remaining.

Mr. TAUZIN. Mr. Speaker, we reserve the balance of our time. If anyone wants to use some more time at this time would be a good time to do it.

Mr. DINGELL. Mr. Speaker, I reserve the balance of my time, and I want to yield it to our leader.

Mrs. JOHNSON of Connecticut. Mr. Speaker, I yield myself 30 seconds.

This is a historic evening. It is our opportunity tonight to provide prescription drugs to all seniors under Medicare as an entitlement and to do it in a way that is fair, simple and generous and sustainable. It is our opportunity tonight to modernize the benefit programs under Medicare to deal with chronic care for our seniors, a big concern for them, and to structure Medicare in such a way that it will be sustainable, the dollars will be there and Medicare will be able to provide the health retirement security in the future that it has in the past.

I urge support of H.R. 1 and defeat of the substitute.
CALL OF THE HOUSE
Mr. TAUZIN. Mr. Speaker, I move a call of the House.

The SPEAKER pro tempore. A quorum is not present.

A call of the House was ordered.

The call was taken by electronic device, and the following Members responded to their names:

[Roll No. 329]

ANSWERED "PRESENT"—421

The SPEAKER pro tempore (Mr. DELAY), the majority leader.

Mr. DELAY. Mr. Speaker, I want to inform the House that the Members present have recorded their presence by electronic device, a quorum. Under the rule, further proceedings under the call are dispensed with.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. HASTINGS of Washington) (during the vote). There are 2 minutes remaining in this vote.

The SPEAKER pro tempore. On this rollcall, 421 Members have recorded their presence by electronic device, a quorum.

Under the rule, further proceedings under the call are dispensed with.

MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003

The SPEAKER pro tempore. The gentleman from Michigan (Mr. DINGELL) is recognized.

Mr. DINGELL. Mr. Speaker, I yield the balance of my time to the distinguished gentleman from Arkansas (Mr. BERRY).

The SPEAKER pro tempore. The gentleman from Arkansas (Mr. BERRY) is recognized.

Mr. BERRY. Mr. Speaker, we are here this evening on a very serious matter. It can literally mean life or death for many of our elderly citizens. Our great Nation was founded, and has so far been successful, based on the self-evident truth in the Declaration of Independence that all men are created equal. They are endowed by their Creator with certain inalienable rights, and that among these are life, liberty, and the pursuit of happiness.

Mr. Speaker, these founding truths were fought for by a firm commitment from our Founding Fathers, the last sentence in the Declaration of Independence. It says: In support of this declaration, with a firm reliance on the protection of Divine Providence, we mutually pledge to each other our lives, our fortune, and our sacred honor.

Mr. Speaker, I think that those men would be heartbroken to see what happens here this evening. As I said earlier, the Republicans are in charge. We recognize that. You can do what you want to do. You do, and I give you credit, for publicly acknowledging that you want to destroy Medicare. You do, and I give you credit, for some of your leaders publicly acknowledging that you would put us into bankruptcy just so we can make the government smaller. So we can do away with certain social programs that you do not like. And I give you credit for that. In fact, I think some of you, and I have seen it, have publicly proclaimed you are proud of it.

My dilemma is, why would you want to do what you are trying to do tonight to the women and men who went through the Depression, fought World War II, and then built this great Nation into what it is today and turned it over to my generation?

I had a little cute remark in there, but I am not going to use it because I think this is far too serious. The business we take up this evening. A government should not make poor people poorer, rich people richer. It should not create a situation where no one has to be responsible, and it should not make it possible for a particular person to be able to take advantage of others because of an act of that government.

If you do what you are talking about doing, you will make that exact thing possible. You will make it possible for insurance companies and pharmaceutical companies to rob the senior citizens of this country.

Mr. Speaker, I want to commend all those that have worked so hard on probably the most important issue that most of us will vote on in our career. There are very few times that you are going to have a vote like this.