

## AMENDMENT NO. 3400

At the request of Mr. CARDIN, the names of the Senator from Michigan (Mr. LEVIN) and the Senator from Maryland (Ms. MIKULSKI) were added as cosponsors of amendment No. 3400 proposed to H.R. 3043, a bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2008, and for other purposes.

## AMENDMENT NO. 3440

At the request of Mr. BINGAMAN, the names of the Senator from Maine (Ms. SNOWE), the Senator from Montana (Mr. BAUCUS), the Senator from Massachusetts (Mr. KERRY), the Senator from Connecticut (Mr. LIEBERMAN), the Senator from Michigan (Ms. STABENOW), the Senator from Ohio (Mr. BROWN), the Senator from Missouri (Mrs. MCCASKILL) and the Senator from Michigan (Mr. LEVIN) were added as cosponsors of amendment No. 3440 proposed to H.R. 3043, a bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2008, and for other purposes.

At the request of Ms. LANDRIEU, her name was added as a cosponsor of amendment No. 3440 proposed to H.R. 3043, supra.

## AMENDMENT NO. 3447

At the request of Mr. SMITH, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of amendment No. 3447 intended to be proposed to H.R. 3043, a bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2008, and for other purposes.

## STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. ROBERTS:

S. 2218. A bill to provide for the award of a military service medal to members of the Armed Forces who were exposed to ionizing radiation as a result of participation in a test of atomic weapons; to the Committee on Armed Services.

Mr. ROBERTS. Mr. President, I want to take a moment to honor those veterans who have served their Nation as quiet heroes. These quiet heroes, otherwise known as Atomic Veterans, were exposed unknowingly to ionizing radiation resulting from atomic testing conducted between 1945-1963.

Sacrifice in the service of your country can take many different forms. We see it everyday in our military efforts in Iraq and Afghanistan. We see it in the hospital beds of Walter Reed and VA hospitals nationwide. It is our duty as Americans, to honor the sacrifice made by our Nation's servicemembers.

In the case of the Atomic Veterans, sacrifice was not necessarily something that happened on the battlefield, nor

on the navel fleet. The price that many Atomic Veterans paid came due after their years of military service, when enduring mysterious cancers and other medical conditions related to their exposure to ionizing radiation. Their fight continues and the time is long overdue to recognize what, for some, has become the ultimate sacrifice.

In recognition of the silent sacrifices made by these American heroes, I am introducing the Atomic Veterans Medal Act. It is the Senate companion to H.R. 3471, offered by my colleague, Congressman TODD TIAHRT, in the House. We owe a debt of gratitude to brave Americans who have worn the uniform. It is my hope that this measure helps to show the respect and honor these Atomic Veterans deserve.

By Mr. DURBIN (for himself, Mr. AKAKA, Ms. STABENOW, Mrs. BOXER, and Mr. OBAMA):

S. 2219: A bill to amend title XVIII of the Social Security Act to deliver a meaningful benefit and lower prescription drug prices under the Medicare Program; to the Committee on Finance.

Mr. DURBIN. Mr. President, nearly 4 years have passed since Congress enacted the Medicare Modernization Act. Adding a prescription drug benefit to Medicare was long overdue, and many senior citizens and people with disabilities are relieved to finally have drug coverage.

But the drug benefit was not structured like the rest of Medicare. For all other Medicare benefits, seniors can choose whether to receive benefits directly through Medicare or through a private insurance plan. The overwhelming majority choose the Medicare-run option for their hospital and physician coverage.

No such choice is available for prescription drugs. Medicare beneficiaries must enroll in a private insurance plan to obtain drug coverage.

A report released today by the Medicare Rights Center, with the support of Consumers Union, identifies the problems this decision to rely exclusively on private drug plans has created.

Seniors are having trouble identifying which of the dozens of private drug plans works best for them. Anyone who has visited a senior center or spoken with an elderly relative knows that the complexity of the drug benefit has created much confusion.

Each drug plan has its own premium, cost-sharing requirements, list of covered drugs, and pharmacy network. After you have identified the right drug plan, you have to go through the whole process again at the end of the year because your plan may have changed the drugs it covers or added new restrictions on how to access covered drugs.

Medicare beneficiaries often cannot obtain the drugs they need because they are trapped in an appeals process that the Medicare Rights Center calls "hopelessly dysfunctional." Drug plans

often do not tell beneficiaries that they can appeal a drug plan's decision to deny coverage of a drug, even though they are required to do so. Beneficiaries who do appeal soon find that it is a long and difficult process.

The complexity of the Medicare drug benefit also has made beneficiaries more vulnerable to aggressive and deceptive marketing practices. Some insurers try to steer seniors into more profitable Medicare Advantage plans. Some seniors have been signed up for Medicare Advantage plans without their knowledge, and, unfortunately, there have also been unscrupulous insurance agents who have misrepresented what benefits would be covered.

Adding to the frustration with the program so far is accumulating evidence that private drug plans have not been effective negotiators, which means seniors end up paying more than they should.

Drug prices are higher in private Medicare drug plans than drug prices available through the Veterans Administration, Medicaid, and other countries like Canada.

A report by the House Oversight and Government Reform Committee estimated that taxpayers and Medicare beneficiaries would have saved almost \$15 billion in 2007 if administrative expenses in the drug program were as low as the traditional government-run Medicare program and if drug prices were the same as Medicaid levels.

It should come as no surprise then that the average beneficiary who stays in their current Medicare drug plan will see their monthly premiums increase 21 percent in 2008.

Today, I am introducing the Medicare Prescription Drug Savings and Choice Act. The bill would create a Medicare-operated drug plan that would compete with private drug plans and would require the Health and Human Services Secretary to negotiate with drug companies to lower drug prices.

This is the kind of drug plan that Medicare beneficiaries are looking for. According to a survey by the Kaiser Family Foundation,  $\frac{2}{3}$  of seniors want the option of getting drug coverage directly from Medicare, and over 80 percent favor allowing the government to negotiate with drug companies for lower prices.

The Health and Human Services Secretary would have the tools to negotiate with drug companies, including the use of drug formulary. The best medical evidence would determine which drugs are covered in the formulary, and the formulary would be used to promote safety, appropriate use of drugs, and value.

The bill would establish an appeals process that is efficient, imposes minimal administrative burdens, and ensures timely procurement of nonformulary drugs or nonpreferred drugs when medically necessary.

The Secretary would also develop a system for paying pharmacies that

would include the prompt payment of claims.

Seniors want the ability to choose a Medicare-administered drug plan. Let us give them this option, just as they have this choice with every other benefit covered by Medicare. Many seniors will find direct Medicare coverage to be a simpler, more dependable, and less costly option than private drug plans.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be placed in the RECORD, as follows:

S. 2219

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Medicare Prescription Drug Savings and Choice Act of 2007”.

**SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION.**

(a) IN GENERAL.—Subpart 2 of part D of the Social Security Act is amended by inserting after section 1860D-11 (42 U.S.C. 1395w-111) the following new section:

“MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION

“SEC. 1860D-11A. (a) IN GENERAL.—Notwithstanding any other provision of this part, for each year (beginning with 2009), in addition to any plans offered under section 1860D-11, the Secretary shall offer one or more medicare operated prescription drug plans (as defined in subsection (c)) with a service area that consists of the entire United States and shall enter into negotiations in accordance with subsection (b) with pharmaceutical manufacturers to reduce the purchase cost of covered part D drugs for eligible part D individuals who enroll in such a plan.

“(b) NEGOTIATIONS.—Notwithstanding section 1860D-11(i), for purposes of offering a medicare operated prescription drug plan under this section, the Secretary shall negotiate with pharmaceutical manufacturers with respect to the purchase price of covered part D drugs in a Medicare operated prescription drug plan and shall encourage the use of more affordable therapeutic equivalents to the extent such practices do not override medical necessity as determined by the prescribing physician. To the extent practicable and consistent with the previous sentence, the Secretary shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, including the use of a formulary and formulary incentives in subsection (e), to reduce the purchase cost of covered part D drugs.

“(c) MEDICARE OPERATED PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this part, the term ‘medicare operated prescription drug plan’ means a prescription drug plan that offers qualified prescription drug coverage and access to negotiated prices described in section 1860D-2(a)(1)(A). Such a plan may offer supplemental prescription drug coverage in the same manner as other qualified prescription drug coverage offered by other prescription drug plans.

“(d) MONTHLY BENEFICIARY PREMIUM.—

“(1) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The monthly beneficiary premium for qualified prescription drug coverage and access to negotiated prices described in section 1860D-2(a)(1)(A) to be charged under a

medicare operated prescription drug plan shall be uniform nationally. Such premium for months in 2009 and each succeeding year shall be based on the average monthly per capita actuarial cost of offering the medicare operated prescription drug plan for the year involved, including administrative expenses.

“(2) SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—Insofar as a medicare operated prescription drug plan offers supplemental prescription drug coverage, the Secretary may adjust the amount of the premium charged under paragraph (1).

“(e) USE OF A FORMULARY AND FORMULARY INCENTIVES.—

“(1) IN GENERAL.—With respect to the operation of a medicare operated prescription drug plan, the Secretary shall establish and apply a formulary (and may include formulary incentives described in paragraph (2)(C)(ii)) in accordance with this subsection in order to—

“(A) increase patient safety;

“(B) increase appropriate use and reduce inappropriate use of drugs; and

“(C) reward value.

“(2) DEVELOPMENT OF INITIAL FORMULARY.—

“(A) IN GENERAL.—In selecting covered part D drugs for inclusion in a formulary, the Secretary shall consider clinical benefit and price.

“(B) ROLE OF AHRQ.—The Director of the Agency for Healthcare Research and Quality shall be responsible for assessing the clinical benefit of covered part D drugs and making recommendations to the Secretary regarding which drugs should be included in the formulary. In conducting such assessments and making such recommendations, the Director shall—

“(i) consider safety concerns including those identified by the Federal Food and Drug Administration;

“(ii) use available data and evaluations, with priority given to randomized controlled trials, to examine clinical effectiveness, comparative effectiveness, safety, and enhanced compliance with a drug regimen;

“(iii) use the same classes of drugs developed by United States Pharmacopeia for this part;

“(iv) consider evaluations made by—

“(I) the Director under section 1013 of Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

“(II) other Federal entities, such as the Secretary of Veterans Affairs; and

“(III) other private and public entities, such as the Drug Effectiveness Review Project and Medicaid programs; and

“(v) recommend to the Secretary—

“(I) those drugs in a class that provide a greater clinical benefit, including fewer safety concerns or less risk of side-effects, than another drug in the same class that should be included in the formulary;

“(II) those drugs in a class that provide less clinical benefit, including greater safety concerns or a greater risk of side-effects, than another drug in the same class that should be excluded from the formulary; and

“(III) drugs in a class with same or similar clinical benefit for which it would be appropriate for the Secretary to competitively bid (or negotiate) for placement on the formulary.

“(C) CONSIDERATION OF AHRQ RECOMMENDATIONS.—

“(1) IN GENERAL.—The Secretary, after taking into consideration the recommendations under subparagraph (B)(v), shall establish a formulary, and formulary incentives, to encourage use of covered part D drugs that—

“(I) have a lower cost and provide a greater clinical benefit than other drugs;

“(II) have a lower cost than other drugs with same or similar clinical benefit; and

“(III) drugs that have the same cost but provide greater clinical benefit than other drugs.

“(ii) FORMULARY INCENTIVES.—The formulary incentives under clause (i) may be in the form of one or more of the following:

“(I) Tiered copayments.

“(II) Reference pricing.

“(III) Prior authorization.

“(IV) Step therapy.

“(V) Medication therapy management.

“(VI) Generic drug substitution.

“(iii) FLEXIBILITY.—In applying such formulary incentives the Secretary may decide not to impose any cost-sharing for a covered part D drug for which—

“(I) the elimination of cost sharing would be expected to increase compliance with a drug regimen; and

“(II) compliance would be expected to produce savings under part A or B or both.

“(3) LIMITATIONS ON FORMULARY.—In any formulary established under this subsection, the formulary may not be changed during a year, except—

“(A) to add a generic version of a covered part D drug that entered the market;

“(B) to remove such a drug for which a safety problem is found; and

“(C) to add a drug that the Secretary identifies as a drug which treats a condition for which there has not previously been a treatment option or for which a clear and significant benefit has been demonstrated over other covered part D drugs.

“(4) ADDING DRUGS TO THE INITIAL FORMULARY.—

“(A) USE OF ADVISORY COMMITTEE.—The Secretary shall establish and appoint an advisory committee (in this paragraph referred to as the ‘advisory committee’)—

“(i) to review petitions from drug manufacturers, health care provider organizations, patient groups, and other entities for inclusion of a drug in, or other changes to, such formulary; and

“(ii) to recommend any changes to the formulary established under this subsection.

“(B) COMPOSITION.—The advisory committee shall be composed of 9 members and shall include representatives of physicians, pharmacists, and consumers and others with expertise in evaluating prescription drugs. The Secretary shall select members based on their knowledge of pharmaceuticals and the Medicare population. Members shall be deemed to be special Government employees for purposes of applying the conflict of interest provisions under section 208 of title 18, United States Code, and no waiver of such provisions for such a member shall be permitted.

“(C) CONSULTATION.—The advisory committee shall consult, as necessary, with physicians who are specialists in treating the disease for which a drug is being considered.

“(D) REQUEST FOR STUDIES.—The advisory committee may request the Agency for Healthcare Research and Quality or an academic or research institution to study and make a report on a petition described in subparagraph (A)(ii) in order to assess—

“(i) clinical effectiveness;

“(ii) comparative effectiveness;

“(iii) safety; and

“(iv) enhanced compliance with a drug regimen.

“(E) RECOMMENDATIONS.—The advisory committee shall make recommendations to the Secretary regarding—

“(i) whether a covered part D drug is found to provide a greater clinical benefit, including fewer safety concerns or less risk of side-effects, than another drug in the same class that is currently included in the formulary and should be included in the formulary;

“(ii) whether a covered part D drug is found to provide less clinical benefit, including greater safety concerns or a greater risk of side-effects, than another drug in the same class that is currently included in the formulary and should not be included in the formulary; and

“(iii) whether a covered part D drug has the same or similar clinical benefit to a drug in the same class that is currently included in the formulary and whether the drug should be included in the formulary.

“(F) LIMITATIONS ON REVIEW OF MANUFACTURER PETITIONS.—The advisory committee shall not review a petition of a drug manufacturer under subparagraph (A)(ii) with respect to a covered part D drug unless the petition is accompanied by the following:

“(i) Raw data from clinical trials on the safety and effectiveness of the drug.

“(ii) Any data from clinical trials conducted using active controls on the drug or drugs that are the current standard of care.

“(iii) Any available data on comparative effectiveness of the drug.

“(iv) Any other information the Secretary requires for the advisory committee to complete its review.

“(G) RESPONSE TO RECOMMENDATIONS.—The Secretary shall review the recommendations of the advisory committee and if the Secretary accepts such recommendations the Secretary shall modify the formulary established under this subsection accordingly. Nothing in this section shall preclude the Secretary from adding to the formulary a drug for which the Director of the Agency for Healthcare Research and Quality or the advisory committee has not made a recommendation.

“(H) NOTICE OF CHANGES.—The Secretary shall provide timely notice to beneficiaries and health professionals about changes to the formulary or formulary incentives.

“(f) INFORMING BENEFICIARIES.—The Secretary shall take steps to inform beneficiaries about the availability of a Medicare operated drug plan or plans including providing information in the annual handbook distributed to all beneficiaries and adding information to the official public Medicare website related to prescription drug coverage available through this part.

“(g) APPLICATION OF ALL OTHER REQUIREMENTS FOR PRESCRIPTION DRUG PLANS.—Except as specifically provided in this section, any Medicare operated drug plan shall meet the same requirements as apply to any other prescription drug plan, including the requirements of section 1860D-4(b)(1) relating to assuring pharmacy access.”.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D-3(a) of the Social Security Act (42 U.S.C. 1395w-103(a)) is amended by adding at the end the following new paragraph:

“(4) AVAILABILITY OF THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—A medicare operated prescription drug plan (as defined in section 1860D-11A(c)) shall be offered nationally in accordance with section 1860D-11A.”.

(2)(A) Section 1860D-3 of the Social Security Act (42 U.S.C. 1395w-103) is amended by adding at the end the following new subsection:

“(c) PROVISIONS ONLY APPLICABLE IN 2006, 2007, AND 2008.—The provisions of this section shall only apply with respect to 2006, 2007, and 2008.”.

(B) Section 1860D-11(g) of such Act (42 U.S.C. 1395w-111(g)) is amended by adding at the end the following new paragraph:

“(8) NO AUTHORITY FOR FALBACK PLANS AFTER 2008.—A fallback prescription drug plan shall not be available after December 31, 2008.”.

(3) Section 1860D-13(c)(3) of such Act (42 U.S.C. 1395w-113(c)(3)) is amended—

(A) in the heading, by inserting “AND MEDICARE OPERATED PRESCRIPTION DRUG PLANS” after “FALLBACK PLANS”; and

(B) by inserting “or a medicare operated prescription drug plan” after “a fallback prescription drug plan”.

(4) Section 1860D-16(b)(1) of such Act (42 U.S.C. 1395w-116(b)(1)) is amended—

(A) in subparagraph (C), by striking “and” after the semicolon at the end;

(B) in subparagraph (D), by striking the period at the end and inserting “; and”; and

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

“(E) payments for expenses incurred with respect to the operation of medicare operated prescription drug plans under section 1860D-11A.”.

(5) Section 1860D-41(a) of such Act (42 U.S.C. 1395w-151(a)) is amended by adding at the end the following new paragraph:

“(19) MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—The term ‘medicare operated prescription drug plan’ has the meaning given such term in section 1860D-11A(c).”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the enactment of section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

**SEC. 3. IMPROVED APPEALS PROCESS UNDER THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.**

Section 1860D-4(h) of the Social Security Act (42 U.S.C. 1305w-104(h)) is amended by adding at the end the following new paragraph:

“(h) APPEALS PROCESS FOR MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—

“(1) IN GENERAL.—The Secretary shall develop a well-defined process for appeals for denials of benefits under this part under the medicare operated prescription drug plan. Such process shall be efficient, impose minimal administrative burdens, and ensure the timely procurement of non-formulary drugs or exemption from formulary incentives when medically necessary. Medical necessity shall be based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence. Such appeals process shall include—

“(A) an initial review and determination made by the Secretary; and

“(B) for appeals denied during the initial review and determination, the option of an external review and determination by an independent entity selected by the Secretary.

“(2) CONSULTATION IN DEVELOPMENT OF PROCESS.—In developing the appeals process under paragraph (1), the Secretary shall consult with consumer and patient groups, as well as other key stakeholders to ensure the goals described in paragraph (1) are achieved.”.

**SEC. 4. PHARMACY PAYMENT UNDER THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.**

Section 1860D-12(b) of the Social Security Act (42 U.S.C. 1395w-112 (b)) is amended by adding at the end the following new paragraph:

“(4) PHARMACY PAYMENT UNDER THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—

“(A) IN GENERAL.—Under the medicare operated prescription drug plan, the Secretary shall develop a system for payment to pharmacies. Such a system shall include a requirement that the plan shall issue, mail, or otherwise transmit payment for all clean claims submitted under this part within the applicable number of calendar days after the date on which the claim is received.

“(B) DEFINITIONS.—In this paragraph:

“(i) CLEAN CLAIM.—The term ‘clean claim’ means a claim, with respect to a covered

part D drug, that has no apparent defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

“(ii) APPLICABLE NUMBER OF CALENDAR DAYS.—The term ‘applicable number of calendar days’ means—

“(I) with respect to claims submitted electronically, 14 calendar days; and

“(II) with respect to claims submitted otherwise, 30 calendar days.

“(C) PROCEDURES INVOLVING CLAIMS.—

“(i) CLAIMS DEEMED TO BE CLEAN CLAIMS.—

“(I) IN GENERAL.—A claim for a covered part D drug shall be deemed to be a clean claim for purposes of this paragraph if the Secretary does not provide a notification of deficiency to the claimant by the 10th day that begins after the date on which the claim is submitted.

“(II) NOTIFICATION OF DEFICIENCY.—For purposes of subclause (I), the term ‘notification of deficiency’ means a notification that specifies all defects or improprieties in the claim involved and that lists all additional information or documents necessary for the proper processing and payment of the claim.

“(ii) PAYMENT OF CLEAN PORTIONS OF CLAIMS.—The Secretary shall, as appropriate, pay any portion of a claim for a covered part D drug under the medicare operated prescription drug plan that would be a clean claim but for a defect or impropriety in a separate portion of the claim in accordance with subparagraph (A).

“(iii) OBLIGATION TO PAY.—A claim for a covered part D drug submitted to the Secretary that is not paid or contested by the provider within the applicable number of calendar days (as defined in subparagraph (B)) shall be deemed to be a clean claim and shall be paid by the Secretary in accordance with subparagraph (A).

“(iv) DATE OF PAYMENT OF CLAIM.—Payment of a clean claim under subparagraph (A) is considered to have been made on the date on which full payment is received by the provider.

“(D) ELECTRONIC TRANSFER OF FUNDS.—The Secretary shall pay all clean claims submitted electronically by an electronic funds transfer mechanism.”.

By Mr. AKAKA (for himself, Mr. INOUYE, and Mr. MARTINEZ):

S. 2220. A bill to amend the Outdoor Recreation Act of 1963 to authorize certain appropriations; to the Committee on Energy and Natural Resources.

Mr. AKAKA. Mr. President, today I am introducing legislation that will amend the Outdoor Recreation Act of 1963, to further enhance education, instruction and recreation opportunities available in our Nation’s tropical botanical gardens. I wish to also thank my colleagues, Senators DANIEL INOUYE, MEL MARTINEZ and BILL NELSON, for joining me in sponsoring this measure.

Studies have indicated that throughout the world, our plants and their habitats are quickly disappearing. With 90 percent of these species existing in tropical areas, it is imperative that we continue to strive for a greater understanding of how we can preserve these natural resources.

The legislation that I am introducing today, the Outdoor Recreation Act of 1963 Amendments Act, will authorize \$1

million for the National Botanical Gardens in fiscal year 2009, and up to \$500,000 each fiscal year thereafter. These funds are to be matched by State and local governments as well as private individuals.

Since Congress chartered the National Tropical Botanical Gardens in 1964, the gardens have not only thrived and flourished, but have provided valuable research. This research is vital to enriching our lives through not only perpetuating the survival of ecosystems, but preserving the cultural knowledge of these tropical regions.

As we, and the rest of the world, continue to develop rural areas, we slowly deplete our natural resources and place our Nation's tropical plant bio-diversity at risk. It is our responsibility to ensure that measures are in place that will preserve our finite natural resources, or we may find ourselves without the basics for survival.

These gardens serve as safe havens for endangered tropical plants where scientists strive to understand the evolution, structure relationships and qualities of these plants for the future benefit of all Americans. The gardens also serve as a valuable educational tool, where students of all ages go to learn about environmental stewardship and horticultural practices, and discover that science can be fun. The collections at these gardens provide valuable information that conservationists and others utilize to study and determine how to protect these resources by halting further degradation of habitats so that at-risk species will have a better chance of surviving in the future.

I urge my colleagues to support this important legislation in order to ensure that these gardens continue to not only thrive for generations to come, but ensure that these resources will be preserved.

By Mr. GRASSLEY (for himself and Mr. SPECTER):

S. 2221. A bill to amend title XVIII of the Social Security Act to provide for the reporting of sales price data for implantable medical devices; to the Committee on Finance.

Mr. GRASSLEY. Mr. President, I am pleased to introduce today with Senator SPECTER the Transparency in Medical Device Pricing Act of 2007.

As we all know, both parties to a transaction need information in order for the free market to properly work. If only one party has information, the market does not properly function because you have a one-sided negotiation. The purpose of this legislation is to bring transparency to medical device pricing so that there will be sufficient information available for market forces to truly work.

In the Medicare program, most hospitals receive a single payment for all the health care goods and services provided during a beneficiary's stay. This payment structure is designed to give hospitals incentives to provide efficient, effective, and economical care.

Why? Because when a hospital lowers its costs, more of the Medicare payment can go toward the hospital's bottom line.

Hospitals normally have many resources like consultants or reference materials to help them when they negotiate prices for things like drugs, nursing care, or hospital gowns. Unfortunately, this is not the case with implantable medical devices like pacemakers, stents, and artificial hips and knees.

Hospitals have no way of knowing what a fair market price for a medical device is, because in this one industry there is a veil of secrecy over pricing information. In fact, manufacturers typically require hospitals to agree to secrecy or gag clauses in their contracts. The device makers actually prohibit hospitals from disclosing the price of a medical device to others. So hospitals have no idea of what is a fair price. Instead they must engage in one-sided negotiations with medical device manufacturers.

We all know that there must be enough transparency for market forces to work. The free market, after all, thrives on complete information and open competition—not on gag rules and secrecy clauses.

As a farmer, when I go out and buy a tractor, I first go out and talk to a number of people to help me figure out what is a fair price. Having this information puts me on equal footing with the dealer when we negotiate the price. After all, I don't want to be taken to the cleaners.

Today, there is no level playing field when hospitals negotiate with device manufacturers. It shows. This is a major reason why many hospitals pay absurdly more than others for the same medical device. The inflated prices many hospitals pay have implications for the health care system on multiple levels.

First, higher medical device costs take up more of the Medicare payment. That means hospitals have less to spend on other crucial components of care such as staff. And hospitals have less of the Medicare payment to devote toward their bottom line. So they have less money for activities to improve hospital quality and safety. They have less money to spend on health information technology systems. Most importantly, they have less money to keep their doors open and provide care to Medicare beneficiaries. In rural areas in my state where hospitals are barely squeaking by, this is a problem.

Also, I want to point out how hospitals paying more than the fair market price for medical devices adds to skyrocketing entitlement spending. Medicare hospital payments are updated every year. The update takes into account the increased cost of goods and services used to provide care to beneficiaries. Let us say medical device prices are higher than they should be. As a result, Medicare hospital payment updates and Medicare spending will rise faster than they should.

Also, let us remember that there are cost-sharing requirements for certain hospital services. And so Medicare beneficiaries will be paying more out-of-pocket than they should.

All this adds up to one thing: a need for greater transparency in medical device pricing. My good friend and colleague, Senator SPECTER, and I have developed a way to provide greater transparency.

The Transparency in Medical Device Pricing Act of 2007 would bring this needed transparency to medical device pricing by building on current initiatives at the Department of Health and Human Services, HHS. Under the act, here are some conditions device manufacturers would have to receive direct or indirect payments under Medicare, Medicaid, or SCHIP. Every quarter they would have to submit to the HHS Secretary data on average and median sales prices for all medical devices that are implanted during inpatient and outpatient procedures. Manufacturers would be subject to civil money penalties from \$10,000 to \$100,000 for failure to report or misrepresentations of price data.

Collecting such data is not new to HHS. The Secretary has been collecting average sales price data for drugs covered under Part B of the Medicare program for a number of years now.

The Secretary would also be required to make the data available to the public on the website of the Centers for Medicare & Medicaid Services, CMS. CMS would have to update the website on a quarterly basis.

Again, this is nothing new at HHS. It has been promoting transparency in Medicare for quite some time. The Secretary already publicly reports quality and price data of various Medicare providers. This is so beneficiaries can use these resources when selecting a provider.

Publicly reporting implantable medical device pricing would help hospitals negotiate fair prices. For once, they would have a resource to consult so negotiations would be fairer.

Mr. President, let me be clear. I fully support the medical device industry making a profit. I just think it should not be at the expense of hospitals, beneficiaries and the American taxpayer paying much more than they should. We must let the market work, and markets depend on information.

The Transparency in Medical Device Pricing Act of 2007 would go a long way toward ensuring that free market forces actually work. The act would enable hospitals to obtain medical devices at fair prices.

Mr. SPECTER. Mr. President, with Senator GRASSLEY, I introduce a bill that will help control Medicare spending and will increase transparency in our health care system. Medicare spending is a huge component of the Federal budget. In 2006, Medicare benefit payments totaled \$374 billion and accounted for 12 percent of the Federal budget.

Over the past several months I have received many letters from hospitals, consumer groups, employers, health and welfare funds, and health care journalists about the secrecy that the medical device industry is trying to impose around pricing for implantable medical devices, pacemakers, hip and knee replacements, which hospitals purchase. Hospitals are being told they can't share pricing information with any "third parties," that would include patients, physicians, auditors, and consultants. The hospitals are not the ultimate payers. The payers are patients and those who provide health insurance coverage, which includes small businesses, large employers, and local, State, and Federal Government programs. But the hospitals are the ones who have the role of negotiating fair pricing on behalf of the patients and other payers.

A New York hospital stated in a letter to me that many hospitals, patients, communities and Federal agencies are "prevented from participating in an open and fair marketplace—culminating in inflated pricing and less than optimal cost effective health care." This hospital said that it has an annual health care supplies spend of approximately \$300 million, and although the implantable items such as cardiac pacemakers and orthopedic implants represent only 3 percent of the total items the hospital buys, the expenditures are close to 40 percent of the total spend. Moreover, these devices are characterized by annual cost increases of from 8 percent to 15 percent. Since national sales of implantable devices are approximately \$65 billion annually, with an expected growth in utilization of close to 20 percent, the potential of adding 8 to 15 percent annual price increases to the expenditures clearly demands attention.

A smaller health system in Jackson, MS, reports savings in 2006 of more than \$10 million because it was able to get detailed objective and measurable information that neutralized the arguments from the vendors who were telling them that they were getting the best price. The National Partnership for Women and Families told me that consumers can learn more about the quality and price of a car than they can about these medical devices that are implanted in the body. The Pacific Business Group on Health, a collection of 50 of the Nation's largest purchasers of health care who spend billions of dollars annually to provide health care coverage to more than 3 million employees, retirees and dependents, also wrote to me that the critical strategy for improving the quality of our Nation's health care system is increasing its transparency.

The Transparency in Medical Device Pricing Act of 2007 would require medical device manufacturers, as a condition of receiving direct or indirect payments under Medicare, Medicaid, and SCHIP, to submit to the Secretary of Health and Human Services, on a quar-

terly basis, data on average and median sales prices for all implantable medical devices used in inpatient and outpatient procedures. Manufacturers would be subject to civil monetary penalties from \$10,000 to \$100,000 for failure to report or for misrepresentation of price data. The data would be available to the public on the website of the centers for Medicare and Medicaid Services.

Senator GRASSLEY and I believe this bill will improve the overall quality and efficiency of our health care system and will help ensure that health care programs administered or sponsored by the Federal Government, in particular, promote quality and efficient delivery of health care through 1. the use of health information technology; 2. transparency regarding health care quality and price; and 3. better incentives for those involved in these programs—physicians, hospitals, and beneficiaries. By making important information available in a readily useable manner and in collaboration with similar initiatives in the private sector and nonfederal public sector, we can help control government spending on health care. The rising cost of health care and health insurance is a problem for consumers, small business owners, large employers and union health and welfare funds. This bill says that if you want to do business with the Federal Government, you have got to show us your prices.

#### AMENDMENTS SUBMITTED AND PROPOSED

**SA 3449.** Mr. DURBIN submitted an amendment intended to be proposed to amendment SA 3404 proposed by Mr. SCHUMER (for himself and Mrs. HUTCHISON) to the amendment SA 3325 proposed by Mr. HARKIN (for himself and Mr. SPECTER) to the bill H.R. 3043, making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2008, and for other purposes.

**SA 3450.** Mr. HARKIN (for Mr. DEMINT) proposed an amendment to amendment SA 3325 proposed by Mr. HARKIN (for himself and Mr. SPECTER) to the bill H.R. 3043, supra.

#### TEXT OF AMENDMENTS

**SA 3449.** Mr. DURBIN submitted an amendment intended to be proposed to amendment SA 3404 proposed by Mr. SCHUMER (for himself and Mrs. HUTCHISON) to the amendment SA 3325 proposed by Mr. HARKIN (for himself and Mr. SPECTER) to the bill H.R. 3043, making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2008, and for other purposes; as follows:

On page 2 of the amendment, after line 11, insert the following:

**SEC. 522. (a) FEE FOR RECAPTURE OF UNUSED EMPLOYMENT-BASED IMMIGRANT VISAS.**—Section 106(d) of the American Competitiveness in the Twenty-first Century Act of 2000 (Public Law 106-313; 8 U.S.C. 1153 note), as amend-

ed by section 521, is further amended by adding at the end the following:

"(5) FEE FOR RECAPTURE OF UNUSED EMPLOYMENT-BASED IMMIGRANT VISAS.—

"(A) IN GENERAL.—The Secretary of Homeland Security shall impose a fee upon each petitioning employer who uses a visa recaptured from fiscal years 1996 and 1997 under this subsection to provide employment for an alien as a professional nurse, provided that—

"(i) such fee shall be in the amount of \$1,500 for each such alien nurse (but not for dependents accompanying or following to join who are not professional nurses); and

"(ii) no fee shall be imposed for the use of such visas if the employer demonstrates to the Secretary that—

"(I) the employer is a health care facility that is located in a county or parish that received individual and public assistance pursuant to Major Disaster Declaration number 1603 or 1607; or

"(II) the employer is a health care facility that has been designated as a Health Professional Shortage Area facility by the Secretary of Health and Human Services as defined in section 332 of the Public Health Service Act (42 U.S.C. 254e).

"(B) FEE COLLECTION.—A fee imposed by the Secretary of Homeland Security pursuant to this paragraph shall be collected by the Secretary as a condition of approval of an application for adjustment of status by the beneficiary of a petition or by the Secretary of State as a condition of issuance of a visa to such beneficiary."

**(b) CAPITATION GRANTS TO INCREASE THE NUMBER OF NURSING FACULTY AND STUDENTS; DOMESTIC NURSING ENHANCEMENT ACCOUNT.**—Part D of title VIII of the Public Health Service Act (42 U.S.C. 296p et seq.) is amended by adding at the end the following:

#### SEC. 832. CAPITATION GRANTS.

"(a) IN GENERAL.—For the purpose described in subsection (b), the Secretary, acting through the Health Resources and Services Administration, shall award a grant each fiscal year in an amount determined in accordance with subsection (c) to each eligible school of nursing that submits an application in accordance with this section.

"(b) PURPOSE.—A funding agreement for a grant under this section is that the eligible school of nursing involved will expend the grant to increase the number of nursing faculty and students at the school, including by hiring new faculty, retaining current faculty, purchasing educational equipment and audiovisual laboratories, enhancing clinical laboratories, repairing and expanding infrastructure, or recruiting students.

#### "(c) GRANT COMPUTATION.

"(1) AMOUNT PER STUDENT.—Subject to paragraph (2), the amount of a grant to an eligible school of nursing under this section for a fiscal year shall be the total of the following:

"(A) \$1,800 for each full-time or part-time student who is enrolled at the school in a graduate program in nursing that—

"(i) leads to a master's degree, a doctoral degree, or an equivalent degree; and

"(ii) prepares individuals to serve as faculty through additional course work in education and ensuring competency in an advanced practice area.

"(B) \$1,405 for each full-time or part-time student who—

"(i) is enrolled at the school in a program in nursing leading to a bachelor of science degree, a bachelor of nursing degree, a graduate degree in nursing if such program does not meet the requirements of subparagraph (A), or an equivalent degree; and

"(ii) has not more than 3 years of academic credits remaining in the program.