

# America's Healthy Future Act of 2009

## Senate Finance Committee Health Care Reform Bill

On Oct. 13, the Senate Finance Committee approved "America's Health Future Act of 2009" by a margin of 14 to 9. Before it can move forward for a full Senate vote, it must be combined with the Senate Health, Education, Labor and Pensions (HELP) Committee's health reform bill, "Affordable Health Choices Act."

The following are provisions from the bill affecting DME:

### **Sec. 5010. Adjustments to the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Acquisition Program.**

#### Present Law

Medicare Part B covers a wide variety of durable medical equipment, prosthetics, orthotics, and other medical supplies (DMEPOS) if they are medically necessary and are prescribed by a physician.

Medicare pays for most durable medical equipment (DME) on the basis of a fee schedule. The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108-173) required the Secretary to establish a competitive acquisition program for specified durable medical equipment; the single payment amount derived from the competitive acquisition program would replace the Medicare fee schedule payments. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-271) delayed the phase-in and made changes to the program. The program is to be phased-in, starting in nine of the largest metropolitan statistical areas (MSAs) in 2009 (round one), expanding to an additional 70 of the largest MSAs in 2011 (round two), and remaining areas after 2011.

Starting in 2011, the Secretary has the authority to use information on payments determined in competitive acquisition areas to adjust payments for items and services in non-competitive acquisition areas. Before 2015, the following three types of areas are exempt from the competitive acquisition program: (a) rural areas; (b) metropolitan statistical areas (MSA) not selected under round one or round two with a population of less than 250,000; and (c) areas with a low population density within an MSA that is otherwise selected to be part of the competitive acquisition program.

#### Committee Bill

The Committee Bill would require the Secretary to expand the number of areas to be included in Round Two of the program from 79 of the largest MSAs to 100 of the largest MSAs by including the next 21 largest MSAs by population. The provision would also require that the Secretary extend the competitive acquisition program, or apply competitively-bid rates, to the remaining areas by 2016. All other provisions in Present Law would remain in place, such as the Secretary's discretion to exempt rural areas and areas with low population density within an MSA.

### **Sec. 3136. Revision of Payment for Power-Driven Wheelchairs.**

#### Present Law

Wheelchairs, including power-driven wheelchairs, are covered by Medicare under the capped-rental category of the durable medical equipment (DME) benefit. Medicare pays for power-driven wheelchairs in one of two ways: either Medicare will pay the supplier a monthly rental amount during the beneficiary's period of medical need (though payments are not to exceed 13 continuous months), or the payment is made on a lump-sum basis at the time the supplier furnishes the chair if the beneficiary chooses the lump-sum payment option. If the reasonable lifetime of a power-driven wheelchair is reached, or the wheelchair is lost or irreparably damaged, Medicare will pay for a replacement. The beneficiary may elect to have the replacement purchased through either monthly rental payments not to exceed 13 months, or a lump-sum payment.

Rental payments for wheelchairs are statutorily determined as ten percent of the purchase price of the chair for each of the first three months of rental and 7.5 percent of the purchase price for each of the remaining ten months of the rental period.

Medicare pays for most DME on the basis of a fee schedule. However, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, 108-173) required the Secretary to establish a competitive acquisition program for specified durable medical equipment; the competitive acquisition program would replace the Medicare fee schedule payments. The program is to be phased-in, starting in nine of the largest metropolitan statistical areas (MSAs) in 2009; expanding to 80 of the largest MSAs in 2011 and remaining areas after 2011.

#### Committee Bill

Starting January 1, 2011, the Committee Bill would limit the option to purchase a power-driven wheelchair with a lump-sum payment only to complex, rehabilitative power wheelchairs. The lump-sum payment option would be eliminated for all other wheelchairs. The provision would also eliminate the lump-sum purchase option for replacing a wheelchair for all chairs except complex, rehabilitative power wheelchairs. This provision would not apply to competitive acquisition areas prior to January 1, 2011.

Also starting January 1, 2011, the Committee Bill would change the calculation of the rental payment for power-driven wheel chairs. The rental payment for power-driven wheelchairs would be 15 percent of the purchase price for each of the first three months (instead of ten percent), and six percent of the purchase price for each of the remaining ten months of the rental period (instead of 7.5 percent).

#### Productivity Adjustments:

Certain durable medical equipment. The productivity adjustment factor would be applied to the CPI-U used to increase the fee schedules for certain durable medical equipment (DME) beginning in CY2011. Under Present Law, certain DME are to receive a payment increase of CPI-U plus 2 percentage points in CY2014. The provision would eliminate the two percentage point increase.

Prosthetic devices, orthotics, and prosthetics. The productivity adjustment factor would be applied to the CPI-U update for the applicable fee schedule for this DME category starting in CY2011.

Other items. The productivity adjustment factor would be applied to the CPI-U update for this DME category starting in CY2011.

#### Sec. 6009. Imposition of Annual Fee on Medical Device Manufacturers and Importers.

##### Present Law

IRS authority to assess and collect taxes is generally provided in subtitle F of the Code (secs. 6001 -7874), relating to procedure and administration. That subtitle establishes the rules governing both how taxpayers are required to report information to the IRS and to pay their taxes, as well as their rights. It also establishes the duties and authority of the IRS to enforce the Federal tax law, and sets forth rules relating to judicial proceedings involving Federal tax.

Present law does not impose an annual sector fee on companies that manufacture or import medical devices for sale in the United States.

##### Committee Bill

*The Committee Bill imposes a fee each calendar year on each covered entity engaged in the business of manufacturing or importing medical devices offered for sale in the United States. The aggregate fee under the provision is \$4 billion payable annually beginning in 2010. The fee is due each calendar year on a date to be determined by the Secretary, but in no event later than September 30th. Under the provision, the aggregate fee would be apportioned among the covered entities each year based on each entity's relative share of gross receipts from medical device sales taken into account for the prior year.*

A covered entity is defined under the provision as any manufacturer or importer with gross receipts from medical device sales. For purposes of the provision, covered entity includes all persons treated as a single employer under subsection (a) or (b) of section 52 or subsection (m) or (o) of section 414. The otherwise applicable exclusion of foreign corporations under those rules is disregarded for these purposes.

Under the Committee Bill, medical device sales means sales for use in the United States of any medical device, other than the sales of a medical device that has been classified in class II under section 513 of the Federal Food, Drug, and Cosmetic Act and is primarily sold to consumers at retail for not more than \$100 per unit, or has been classified in class I under such section. A medical device is any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act intended for humans. The Secretary has authority under this provision to publish guidance necessary to carry out the purposes of this provision. It is expected that the Secretary will provide guidance as to class II items primarily sold to consumers at retail for not more than \$100 per unit, such as a list of class II items excluded under this provision. The provision is intended to exclude low cost items (such as pregnancy tests, contact lenses, and blood pressure monitors) that are normally sold directly to consumers through retail outlets. The Committee intends that a unit is an entire item as typically sold (for example a box of 30 disposable contact lenses), and does not refer to an item's component parts. Additionally the Secretary may publish guidance for the treatment of gross receipts from the sale of medical devices by a covered entity directly to another covered entity for use as a material in the manufacture or production of, or as a component part of a medical device for subsequent sale in order to eliminate double inclusion of the gross receipts from such sales.

Under the Committee Bill, each covered entity is required to file an annual report of its gross receipts from medical device sales for the preceding calendar year. Under the provision, a covered entity's individual assessment for each calendar year is the total fee multiplied by the ratio of (1) the covered entity's gross receipts from medical device sales taken into account during the preceding calendar year to (2) the aggregate gross receipts from medical device sales of all covered entities taken into account during such preceding calendar year.

Sales taken into account for this purpose includes zero percent of a covered entity's gross receipts from medical device sales for the preceding calendar year up to \$5 million; 50 percent of a covered entity's gross receipts from medical device sales for the preceding calendar year over \$5 million and up to \$25 million; and 100 percent of a covered entity's gross receipts from medical device sales for the preceding calendar year over \$25 million.

The following is an example of how the relative market share would be determined if the medical device market included three covered entities, Company A with gross receipts from covered medical device sales of \$1 million, Company B with gross receipts from covered medical device sales of \$20 million and Company C with gross receipts from covered medical device sales of \$979 million for a combined market of \$1 billion.

#### Effective Date

The Committee Bill is effective for calendar years beginning after 2009. The fee is allocated based on the market share of gross receipts from medical device sales for calendar years beginning after December 31, 2008.

### **Sec. 3110. Exemption of Certain Pharmacies from Accreditation Requirements**

#### Present Law

MMA required the Secretary to establish and implement quality standards for suppliers of durable medical equipment, prosthetics and supplies (DMEPOS) under Part B of Medicare. MIPPA requires DMEPOS suppliers to prove their compliance with the quality standards by being accredited by October 1, 2009. MIPPA, however, exempted eligible professionals from having to comply with the accreditation requirement unless the standards and accreditation requirements being applied were specifically designed to be applied to those professionals. The statute defines the following as eligible professionals: physicians, physical or occupational therapists, qualified speech-language pathologists, qualified audiologists, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, or registered dietitians or nutrition professionals. The Secretary was given authority to exempt additional professionals from the accreditation requirements. Pharmacists and pharmacies were not listed as exempt from the accreditation requirements.

## Committee Bill

Effective January 1, 2010, the Committee Bill would make certain pharmacies eligible for an exemption from the accreditation requirements. A pharmacy would be exempt from the accreditation requirements under the following circumstances: (1) the pharmacy submits an attestation that its total Medicare DMEPOS billings are, and continue to be, less than a rolling three year average of five percent of total pharmacy sales; (2) the pharmacy submits an attestation that it is enrolled as a provider of durable medical equipment, prosthetics, orthotics, and supplies under the Medicare program for at least 5 years and has had no adverse determination against it for the last five years due to fraud; and (3) the pharmacy is willing to submit documentation to the Secretary (based on a random sample of pharmacies) that would allow the Secretary to verify the information in (1) and (2). The documentation submitted for (3) would be required to consist of an accountant certification or filing of tax returns by the pharmacy.

The provision would also allow the Secretary to determine accreditation standards that are more appropriate for pharmacies. The Secretary would have the authority to implement this amendment by program instruction or otherwise.

### **Sec. 5005. Physicians who Order Items and Services Required to be Medicare Enrolled Physicians or Eligible Professionals.**

#### Present Law

Medicare statute defines –eligible professionals|| as physicians, certain types of practitioners (i.e., physician

assistants, nurse practitioners, clinical social workers, and others), physical or occupational therapists, qualified speech language pathologists, or qualified audiologists.

#### Committee Bill

Beginning January 1, 2010, the Committee Bill would require durable medical equipment or home health services to be ordered by a Medicare eligible professional or physician enrolled in the Medicare program. The Secretary would have the authority to extend these requirements to other Medicare items and services, including covered Part D drugs, to reduce fraud, waste, and abuse.

### **Sec. 5007. Face-to-Face Encounter with Patient Required Before Physicians May Certify Eligibility for Home Health Services or Durable Medical Equipment Under Medicare.**

#### Present Law

Home health services are covered under Medicare Parts A and B. In order to receive payment from Medicare, physicians are required to certify and re-certify that specified services (i.e., inpatient psychiatric services, post-hospital extended care services, and home health services) meet certain conditions. In the case of home health services, physicians are required to certify that such services were required because the individual was confined to his home and needed skilled nursing care or physical, speech, or occupational therapy; a plan for furnishing services to the individual has been established; and such services were provided under the care of a physician.

In the case of DME, the Secretary is authorized to require that payment be made for specified covered items and services only if a physician has submitted to the supplier a written order for the item.

#### Committee Bill

The Committee Bill would require that, after January 1, 2010, physicians have a face-to-face encounter (including through telehealth) with the individual prior to issuing a certification for home health services or DME as a condition for payment under Medicare Parts A and B. The Committee Bill would also apply to physicians

making home health and DME certifications in Medicaid and CHIP. Physicians must document that they had the face-to-face encounter with the individual during the six-month period preceding the certification, or other reasonable timeframe as determined by the Secretary. The Secretary would be authorized to apply the face-to-face encounter requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse.

### Sec. 5011. Expansion of the Recovery Audit Contractor (RAC) Program.

#### Present Law

Recovery Audit Contractors (RACs) are private organizations that contract with the CMS to identify and collect improper payments made in Medicare's fee-for-service (FFS) program. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173), Congress required the Secretary to conduct a three-year demonstration of RACs. However, the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109-432) made the RAC program permanent and mandated its expansion nationwide by January 1, 2010. The RAC program expansion still applied only to Medicare Parts A and B. CMS began the national rollout of the permanent RAC program in 19 states in March 2009.

#### Committee Bill

By December 31, 2010, states would be required to establish contracts, consistent with state law, and similar to the contracts the Secretary has established for the Medicare RAC program, with one or more RACs. These state RAC contracts would be established to identify underpayments and overpayments and to recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

The state Medicaid RAC program would be subject to exceptions and requirements the Secretary may establish for the state RAC program or for individual states. States would be required to provide the Secretary with the following assurances for their RAC programs:

- (1) RACs would be paid only from recovered amounts;
- (2) the contracts would be contingent on collecting overpayments;
- (3) payments may be made in such amounts as the state may specify for identifying underpayments;
- (4) the state has a process for appealing adverse RAC determinations;
- (5) the state's RAC program follows requirements established by the Secretary;
- (6) amounts expended by the state would be considered administrative expenditures (as necessary for the proper and efficient administration of the state plan or waiver);
- (7) recovered amounts would be subject to a state's quarterly expenditure estimates and the funding of the state's share; and
- (8) the state will coordinate the efforts of RACs with other program integrity contractors performing audits of entities receiving payments for any Medicaid services, including coordination with Federal and state law enforcement (the Department of Justice, the Federal Bureau of Investigation, the HHS OIG, and the state Medicaid fraud control unit).

The Secretary, acting through CMS, would be required to coordinate with states on the RAC program expansion to Medicaid, particularly to ensure that each state enters into a contract with a RAC prior to December 31, 2010. The Secretary would be required to promulgate regulations to implement the RAC program expansion to Medicaid, including conditions for Federal financial participation.

In addition, the Secretary would be required to submit an annual report to Congress. The Secretary's report would assess the effectiveness of the RAC program expansion to Medicaid and Medicare Parts C and D and also would include recommendations for expanding or improving the program.