

**MINTZ LEVIN
COHN FERRIS
GLOVSKY AND
POPEO PC**

*Boston
Washington
Reston
New York
New Haven
Los Angeles
London*

*One Financial Center
Boston, Massachusetts 02111
617 542 6000
617 542 2241 fax
www.mintz.com*

**MEDICARE PRESCRIPTION DRUG IMPROVEMENT
AND MODERNIZATION ACT OF 2003**

An Analysis for Medical Device Manufacturers

Prepared for
MASSACHUSETTS MEDICAL DEVICE INDUSTRY COUNCIL
December 2003

COVERAGE AND PAYMENT OF DME

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Act” or the “Medicare Act”). Although the name of the Act suggests that it focuses entirely on prescription drugs, the name is misleading because the Act includes provisions that should be of interest to manufacturers and other suppliers of medical devices. Some of these provisions, including those that establish a statutory deadline for Medicare national coverage decisions and make significant changes in the coverage, payment and quality standards applicable to durable medical equipment (“DME”) and the method for determining new clinical laboratory payments are addressed in detail below.

I. New Quality Initiatives for DME and Certain Medical Supplies

The Medicare Act requires that the Secretary of Health and Human Services (the “Secretary”) establish and implement new quality standards for suppliers of DME and other medical supplies. The quality standards will also govern suppliers of prosthetics and orthotics, prosthetic devices, medical supplies, therapeutic shoes, home dialysis supplies and equipment, parenteral and enteral nutrients, equipment and supplies, blood products and transfusion machines, electromyogram devices, and salivation devices. In order to monitor suppliers’ compliance with these standards, the Secretary must designate one or more independent accreditation organizations within one year of the implementation of such standards. The standards will apply prospectively and must be published on the website of the Centers for Medicare and Medicaid Services (“CMS”). Suppliers must comply with these standards to be eligible to furnish any Medicare reimbursable item or service and to receive or maintain a supplier number used to submit claims for reimbursement.

II. Clinical Conditions for Payment

The Secretary must establish standards governing clinical conditions for payment for covered DME. These standards must specify the types or classes of covered items that require a prescription and a face-to-face examination by a physician or medical professional to be reimbursable under Medicare. In developing these standards, the Secretary must first establish standards for covered items for which the Secretary determines either that: (1) there has been a proliferation of use; (2) there are consistent findings of charges for undelivered items, or (3) there are findings of falsification of documentation used to secure payment. Finally, addressing a recent concern that has been raised, Congress mandated that Medicare will no longer pay for motorized wheelchairs unless there is both a prescription for the item and a face-to-face examination by a physician or other qualified practitioner.

III. Changes to Payment Methodologies for DME, Certain Medical Supplies, and Therapeutic Shoes

The Act substantially alters Medicare’s payment methodology for DME. Prior to the enactment of the Act, Medicare paid for DME according to a fee schedule that classified covered items into six major categories of devices or equipment. Previously, Congress had directed the

Secretary to conduct demonstration projects to test competitive bidding as an alternative to the Medicare fee schedule payment system for DME and medical supplies. In this Act, Congress substantially expands the competitive bidding programs, which will replace Medicare fee schedule methodology beginning in 2007, and freezes the update for DME from 2004 through 2008 followed by subsequent rate controls in the outyears.

a. Competitive Bidding Programs

i. Covered Items and Implementation

The Act establishes a nationwide competitive acquisition program (“Bidding Program” or “Program”) in which suppliers of covered DME and medical supplies must bid for contract awards to furnish their items or services to Medicare beneficiaries. The items subject to the Bidding Program include DME (including items used in infusion and drugs), medical supplies, therapeutic shoes, home dialysis supplies, enteral nutrients, equipment and supplies, blood products and transfusion medicine, electromyogram devices, salivation devices, and off-the-shelf orthotics requiring minimal self-adjustment.

Beginning in 2007, the Bidding Program will start replacing the current payment methodology by phasing-in the Program by geographical area and by item or service. The Program will cover ten of the largest metropolitan areas in 2007, eighty of the largest metropolitan areas by 2009, and additional areas to be added after 2009. To implement the Program, the Secretary must establish “competitive acquisition areas” where demand is sufficient to drive an efficient competitive bidding process. In order to avoid inefficient or adverse outcomes arising in non-competitive markets, the Secretary may exempt from the Bidding Program certain rural areas as well as urban areas with low population density. Nevertheless, the Secretary may not exempt low population density areas if a particular item or service has a national market through mail order capabilities.

In determining which items or services will be subject to the Bidding Program, the Medicare Act authorizes the Secretary to employ his discretion and initially phase-in those items and services with the highest volume and cost, or those items and services determined to have the largest savings potential. Alternatively, the Secretary may exempt from the Bidding Program those items and services for which a competitive bidding process is unlikely to realize savings. The Secretary is also permitted to consider the clinical efficiency and the value of specific items within healthcare procedure codes (“HCPCS”), including whether certain items offer a greater therapeutic advantage to beneficiaries, when deciding which items and services will be subject to the Bidding Program. The Secretary may also rely on the payment amounts realized under the Program to establish fee schedules for DME, off-the-shelf orthotics, and other items and services supplied in areas that are not a designated competitive acquisition areas.

The Bidding Program does not apply to rented DME and oxygen equipment if the rental agreements were entered into before the implementation of the Program. Under the Act, the Secretary must establish a process for grandfathering-in such rental agreements. The suppliers

under grandfathered rental agreements, however, would be obligated to service and replace the rental items.

In order to provide some physician flexibility and avoid regulatory-driven market inefficiencies, the Medicare Act provides several allowances for certain physician-prescribed items and small suppliers of DME. For instance, the Act authorizes the Secretary to establish a process that, notwithstanding the Bidding Program, would enable a physician to prescribe a particular brand or mode of delivery of an item or service. Under this process, a physician could prescribe a specific item within a particular HCPCS code that is necessary to avoid an adverse medical outcome for the Medicare beneficiary. The amount of payment, however, would remain unaffected. Furthermore, the Act protects small suppliers of items and services by requiring that the Secretary adopt measures to ensure that these suppliers have an opportunity to participate in the Bidding Program.

ii. The Conditions for Awarding Contracts, Contract Terms, and Administrative or Judicial Review

Under the Act, the Secretary may not award a contract to a supplier unless the supplier satisfies quality and financial standards established by the Secretary. Further, any contract entered into under the Bidding Program is subject to the terms and conditions specified by the Secretary, and must be re-competed at least once every three years. Additionally, the Secretary must award contracts to multiple entities submitting bids in each area for an item or service, but retains the authority to limit the number of contractors in a competitive acquisition area to the number necessary to meet projected demand. Finally and most importantly, most decisions made pursuant to the Bidding Program are not subject to administrative or judicial review. The Act specifies that the establishment of payment amounts, the awarding of contracts, the designation of competitive acquisition areas, the phased-in implementation, the selection of items and services subject to competition, and the bidding structure remain beyond the scope of the Medicare program's appeals process.

iii. Payment Under the Bidding Program

Payment for competitively priced items and services will be based on bids submitted and accepted, and Medicare will not pay for items or services furnished unless the supplier has submitted a bid and the contract has been awarded. The Secretary will determine a single payment amount for each item or service in each competitive acquisition area. Medicare will pay 80% of the payment amount, and the beneficiary is responsible for paying the remaining 20% (after meeting the Part B deductible). Payment is only permissible on an assignment-related basis, meaning that the supplier must bill Medicare and accept Medicare payment as payment in full, other than co-pays and deductibles.

iv. Monitoring the Bidding Program

In an effort to evaluate the success of the Bidding Program, the Act requires that the Secretary report to Congress concerning savings realized, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the Program. The Inspector General of HHS is to do a report that looks at whether physicians are solicited to prescribe certain brands of items based on profitability by DME suppliers subject to the Bidding Program. Additionally, a Program Advisory and Oversight Committee with members appointed by the Secretary is to be established that will advise the Secretary concerning Program implementation, data collection requirements, the establishment of quality standards, and other related matters.

b. Establishing Rates for DME and Medical Supplies

The Act also freezes payment rates for DME, prosthetic devices, prosthetics and orthotics from 2004 through 2008, while the new competitive bidding process is being implemented. After 2008, payment will increase for those items not included in the Bidding Program by the amount of the consumer price index (“CPI”). The payment amounts for certain items, however, will be reduced in 2005. The items receiving a reduction in payments include oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, and hospital beds and air mattresses. Class III medical devices will receive an increase for 2004, 2005, and 2006 equal to the percentage increase in CPI, but in 2007, any increase is to be determined by the Secretary after reviewing a report to be made by General Accounting Office (“GAO”). After that, the payment update for Class III devices will be the 2007 rate adjusted by the CPI.

c. Payment for Therapeutic Shoes and Inserts

Medicare pays for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease as long as certain requirements are met. The Act creates a new payment methodology for therapeutic shoes that mirrors the reimbursement methodology for orthotics and prosthetics. However, the Secretary retains the authority to establish limits that are lower than those applied to orthotics and prosthetics, if the Secretary finds that shoes and inserts of appropriate quality are readily available at a lower price. Finally, the Act provides that when individuals make modifications to their shoes as permitted by statute, the Secretary must ensure that it establishes a payment rate that will not result in a net expenditure increase for the Medicare program.

IV. Extending Coverage for Preventive Services

The Act requires Medicare to pay for certain preventive services, which have not previously been covered. Beginning in 2005, Medicare will cover an *initial* preventive physical examination, subject to a deductible and beneficiary cost sharing requirements. To qualify for coverage, the examination must be performed within six months after the beneficiary’s initial coverage date under Part B. A covered examination would also include preventive services such as a screening pap and pelvic exam, cardiovascular screening blood tests, diabetes screening

tests, a screening mammography, certain vaccines, and prostate or colorectal cancer screening tests. Other routine clinical laboratory tests furnished during an examination, however, are not included as part of an initial preventive screening examination.

Further, the Act extends Medicare coverage to cardiovascular screening blood tests, which include tests for cholesterol levels and levels of other lipids or triglycerides, as well as tests for other indicators of cardiovascular disease as approved by the Secretary. In consultation with industry organizations, the Secretary will establish standards governing the frequency and type of tests to be administered. The Act limits the frequency of test administration, however, to once within a two-year period.

Prior to enactment of the Act, Medicare paid for diabetes self-management training services provided by physicians in an outpatient setting. Consequently, Medicare paid for blood testing strips and blood glucose monitors, but did not cover laboratory tests used to screen for diabetes. The Act extends coverage to diabetes screening tests given on or after January 1, 2005 to at-risk individuals as evidenced by conditions such as hypertension, dyslipidemia, obesity, and glucose levels, or a combination of factors inclusive of a family history of diabetes.

V. Clinical Laboratories

a. Payment for Clinical Laboratory Tests

Medicare pays for clinical diagnostic laboratory tests based on a fee schedule that is updated annually using the CPI, although Congress has often frozen or limited this update in the past. The Medicare Act again freezes the rates beginning in 2004, and continuing through 2008. This freeze is expected to save Medicare \$7.8 billion.

Currently, a statutory cap, set at 74% of the median for all fee schedules for that particular test, is imposed on the payment amounts. However, new diagnostic laboratory tests, for which no payment amount has previously been established, are limited by a cap equal to 100% of the median. The Act directs the Secretary to promulgate regulations concerning the determination of payment amounts for these new clinical diagnostic laboratory tests, defined as those tests assigned a new HCPCS code on or after January 1, 2005. The regulations must delineate certain responsibilities of the Secretary such as: (1) providing a list, on the Internet or elsewhere, of tests for which payment is being established; (2) holding a public meeting and publishing a notice of that meeting in the Federal Register, and (3) ensuring consideration of public comments in making the payment amount determinations. In addition, the Secretary must publish the data used and the criteria relied upon in establishing payment amounts.

Finally, the Act extends the grandfather granted to clinical laboratories for billing certain physician pathology services. The Beneficiary Improvement and Protection Act of 1997 (“BIPA”) permitted independent laboratories which had existing arrangements with hospitals to bill Medicare directly for the technical component of pathology services provided to patients, but that provision was scheduled to run out. The Act permits Medicare to continue to pay laboratories directly for those services through 2006.

b. Demonstration Competitive Acquisition Program for Clinical Laboratory Tests

The Medicare Act instructs the Secretary to conduct a demonstration program on using competitive acquisition for clinical diagnostic laboratory tests. The same terms and conditions under the Bidding Program for DME and medical supplies would apply to the demonstration program for clinical laboratory tests with the exception of cost-sharing requirements, because lab testing is not currently subject to Medicare copayment or deductible provisions. The CLIA quality standards, which apply generally to clinical diagnostic laboratory tests, will also govern the demonstration project. The demonstration project would target any clinical laboratory tests payable under Medicare that are furnished without a face-to-face encounter between the laboratory provider and the individual. Finally, the Act requires that the Secretary submit a report to Congress concerning the success or progress of the demonstration program by December 31, 2005.

VI. Responding to Changes in Technology

Responding to emerging technologies entering the marketplace, the Medicare Act includes certain provisions that would improve patient and supplier access to information about these technologies, as well as extend coverage to new technologies. Under the Act, the public must have access to the factors relied upon by the Secretary in making a determination about whether an item or service is reasonable and necessary. To publicize these factors, the Secretary must develop a “guidance” process similar to that used by the FDA. Additionally, the Act establishes that the Secretary must provide a national coverage determination within six months of a request when a technology assessment is not required, or within nine months when an assessment is required. A draft of the coverage determination shall be posted on HHS’ website or by another means, followed by a public comment period and then, a final determination. The Secretary must also create a plan that would look for new local coverage determinations that could be applied nationally, and would encourage greater coverage consistency at the local level. Finally, the Secretary must establish revised procedures for issuing temporary national HCPCS codes under Medicare Part B by July 1, 2004.

The Medicare Act also permits the Secretary to cover the routine care provided during or following Category A clinical trials. The Act provides statutory authority for such coverage by specifically prohibiting exclusion of routine care associated with Category A clinical trials.

Furthermore, the Act establishes a Council for Technology and Innovation (the “Council”) at CMS to be composed of senior CMS staff and clinicians. The Council will be responsible for coordinating Medicare’s coverage, coding and payment processes, and the information exchange regarding new technologies and procedures. The Secretary will appoint a Chairperson of the Council who will act as the contact person regarding Medicare coverage, coding, and payment processes.

VII. Study on Portable Diagnostic Ultrasound Services

The Medicare Act specifies that within two years of the enactment of the Act, the GAO will provide a report to Congress concerning its study of portable diagnostic ultrasound services provided to Medicare beneficiaries in skilled nursing facilities. This study will evaluate the types of ultrasound services provided, and the technical training required for technicians administering the tests. In addition, the study will examine the clinical appropriateness of transporting equipment, in lieu of transporting patients to a facility that furnishes such tests.

VIII. Administrative Changes

The Act includes a variety of far-reaching administrative changes that should be of interest to all providers and suppliers. They include changes to the manner in which Medicare interacts with Medicare contractors, who process and pay claims. In addition, the Act will institute a new appeal process for Medicare claims.

a. Medicare Contractors

The Act will change the current manner in which Medicare uses contractors to pay claims. First, it will eliminate the current process of having Fiscal Intermediaries for Part A and carriers for Part B. These functions will be merged together and performed by a new entity, a Medicare Administrative Contractor (“MAC”). Contracts for these MAC functions will now be subject to the federal acquisition process used for other contracts, and will be competitively bid. There are a number of other changes to the contractor process, as well. These amendments are not effective until October, 2005.

b. Medicare Appeals

According to the Act, HHS and the Social Security Administration (“the SSA”) must develop a plan to transfer the responsibility of reviewing Medicare appeals from the SSA to HHS. Currently, administrative law judges (“ALJs”) within the SSA are charged with hearing Medicare appeals from beneficiaries and in certain circumstances, from providers and suppliers. In order to ensure the transferred ALJs remain independent from CMS, the Act directs the Secretary to adopt such measures as positioning the ALJs in an organizationally and functionally separate office, and rendering the ALJs under the exclusive direction of the Secretary.

In addition, the Act alters the requirements for judicial review. Prior to the Act’s enactment, administrative appeals had to be exhausted before an appellant could seek judicial review. The provisions of the Act, however, give an aggrieved beneficiary access to judicial review when it is determined that the ALJ lacks the authority to decide an issue and material facts are not in dispute. Additionally, expedited judicial review is available when the Secretary does not enter into or renew provider agreements.

c. Other Issues Affecting Suppliers

The Medicare Act provides statutory authority for contractors using random prepayment reviews to develop contractor-wide and program-wide error rates. Previously, CMS had used its

administrative authority to initiate these reviews, which often were frustrating for suppliers. The new Act will limit the use of random prepayment reviews and only allows them where CMS needs to develop a contractor program benchmark of claims payment error rates. Non-random reviews are allowable only if there is a likelihood of sustained or high-level payment error.

The Act also limits the use of extrapolation in overpayment cases; that is, where Medicare does a sample of claims and then extrapolates based on the error rate in that sample. Extrapolation would only be permitted where there was a sustained or high level of payment error, and educational efforts had not been successful. The Act also limits the use of “consent settlements,” another process used by CMS in overpayment cases. The Act permits the consent settlement process, but the provider would have to be given a forty-five-day period in which to furnish additional documentation, in situations where a problem is identified. If CMS still thinks a problem exists, after receiving the information, it can give the provider an opportunity to settle or to obtain a statistically valid random sample; however, CMS cannot require the provider to waive its appeal rights, as is done today.

Another important change affecting medical device suppliers concerns the Act’s provision regarding repayment of overpayments. The Act discontinues the practice of giving CMS discretion to negotiate extended repayment terms with providers needing additional time to repay Medicare overpayments. Instead, the Act grants providers likely to suffer a financial hardship if required to pay within thirty days, the explicit ability to repay over between six months and three years. However, the provider must meet certain requirements to demonstrate hardship, and the Secretary need not extend repayment if it has reason to suspect the provider will file for bankruptcy.

The Medicare Act includes several other provisions that will be helpful to suppliers of DME and medical equipment. The first provision provides hearing rights to providers receiving a denial or non-renewal of Medicare coverage. According to the Act, a provider enrollment process must be instituted within six months of enactment that establishes hearing rights for providers. This process would include keeping providers apprised of enrollment application deadlines, and would require the Secretary to consult with providers and suppliers before making any changes to enrollment forms. The second provision within the Act that will enable providers to operate more efficiently is the provision allowing providers to correct minor errors in claims submitted to Medicare. Currently, corrections are not always permitted and Medicare denies claims containing incorrect information. The Act will permit providers to correct minor errors in claims.