



The Patient Protection and Affordable Care Act (PPACA) contains several provisions affecting DMEPOS programs, of which CMS and OIG consider to be high risk.

On March 30, 2010, President Obama signed into law a package of reconciliation amendments to the PPACA, which was enacted on March 23, 2010. The signing of the amendments completed the passage of the sweeping health care reform legislation that has dominated political and health care news for many months. As expected, PPACA contains additional tools to aid the government in identifying and pursuing recovery for allegedly fraudulent, wasteful, or abusive practices.

Because the cost of implementing PPACA (estimated by the Congressional Budget Office to total \$940 million during the first 10 years) will be paid for, in part, by eliminating these fraudulent, wasteful, or abusive practices, all providers and suppliers can expect the government to aggressively use these new tools in the years to come to prevent and recover improper payments and, where determined appropriate, extract substantial financial penalties. DMEPOS suppliers should understand the obligations imposed and the risks presented by PPACA and take action to limit their legal and financial exposure.

This paper summarizes the healthcare impact on DMEPOS operations, the fraud-fighting provisions of the Act, changes to the “Stark” laws, and other miscellaneous statutory changes to the Medicare program.

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Healthcare Bill Impact on DMEPOS (Summary)

1) Medicare eliminates the first-month purchase option for standard power wheelchairs on Jan. 1, 2011. A provision in the Patient Protection and Affordable Care Act (PPACA) eliminates the option. Under the new law, reimbursement for power mobility devices will be stretched over 13 months as a capped rental. The purchase option for complex rehab power chairs will be maintained. Elimination of the purchase option will not apply to any contracts entered into before Jan. 1, 2011, under competitive bidding; winners in the nine Round 1 bid areas will retain the option for the duration of the three-year contract. Payments will also be front-loaded, with 15 percent of the purchase price paid in the first three months — as opposed to the 10 percent under current reimbursement — and 6 percent in months four through 13.

Comment: The legislation does not eliminate “Group 3” from the first-month purchase. Group 3 wheelchairs are prescribed for people unable to stand and pivot to transfer from one location to another due to a neurological condition or myopathy. This is the same class of mobility equipment that was included as an exemption in the Medicare Improvement to Patients and Providers Act (MIPPA) last fall. Currently, Medicare allows a beneficiary to purchase power wheelchair in the first month it is prescribed or rent the equipment for 13 months. This legislation eliminates the early purchase option. Stakeholders argue that seniors and people living with disabilities, who qualify for power wheelchairs, usually suffer from long-term, chronic conditions so they overwhelmingly chose the early purchase. Without the first month purchases, providers say they won't have the cash flow to pay the wheelchair manufacturers or provide other services required. Many equipment suppliers anticipate that they may go out of business or no longer offer power wheelchairs, a development that would make it more difficult for beneficiaries to find providers in their area.

2). Excise tax on medical device manufacturers. Delays the tax by three years to 2013 and converts the industry fee to an excise tax on the first sale for use of medical devices at a rate of 2.3 percent. Exempts from the tax Class I medical devices, eyeglasses, contact lenses, hearing aids, and any device of a type that is generally purchased by the public at retail for individual use. The tax is tax-deductible and would apply to sales of covered devices that occur after Dec. 31, 2012. The reconciliation bill replaced the medical device tax provision in the Senate bill with a different provision that delays the tax until 2013 and exempts Class 1 devices (like canes and walkers) and other items that the HHS Secretary deems a "retail" item purchased for individual use.

Comment: There remains the possibility that DME items will be exempt under the ‘retail’ exemption, but the industry will have to await the Treasury secretary’s determination of what products will be classified as ‘retail.’” In addition, Rep. Erik Paulsen, R-Minn., introduced legislation "that would immediately repeal the job-killing \$20 billion medical device tax," according to a press release from his office. H.R. 5095, called the Defend Medical Innovation Act, has 26 original cosponsors. The tax was included as a provision of the Patient Protection and Affordable Care Act (PPACA), the nation's recently passed health reform law. *"The medical technology industry is an*

American success story, responsible for life-saving technologies and tens of thousands of jobs in Minnesota alone," said Paulsen, who is co-chair of the House Medical Technology Caucus. "Once it takes effect, this tax will harm job growth, slow innovation and raise costs. The right thing to do is stop this tax now, before its negative impact takes hold." PPACA imposes a 2.3 percent sales tax on medical devices to begin in 2013. The tax is estimated to raise \$20 billion over 10 years.

3. Expands Round 2 of the DMEPOS competitive bidding program from the next 70 largest metropolitan statistical areas to an additional 21. Including the nine bidding areas in Round 1, there will now be a total of 100 MSAs in the program. Based on a timeline from CMS, pricing for Round 1 is expected in June with bid winners to be announced in September and implementation in January 2011. This fall, CMS will reveal the product categories to be included in Round 2, and bidding will be conducted in 2011. After payment amounts and contract winners are announced in 2012, Round 2 will go live in January of 2013.

Comment: The most likely metro areas are:

Philadelphia-Camden-Wilmington, PA-
NJ-DE-MD
Washington-Arlington-Alexandria, DC-
VA-MD-WV
Boston-Cambridge-Quincy, MA-NH
Phoenix-Mesa-Scottsdale, AZ
Seattle-Tacoma-Bellevue, WA
St. Louis, MO-IL
Baltimore, MD
Portland-Vancouver-Beaverton, OR
Providence-New Bedford-Fall River, RI-
MA
Buffalo-Niagara Falls, NY
Rochester, NY
Tucson, AZ

Honolulu, HI
Albany-Schenectady-Troy, NY
Oxnard-Thousand Oaks-Ventura, CA
Worcester, MA
Springfield, MA
Sarasota-Bradenton-Venice, FL
Stockton, CA
Poughkeepsie-Newburgh-Middletown,
NY
Boise City, ID
The next three on the list might include:
Madison, WI
Des Moines-West Des Moines, IA
Harrisburg-Carlisle, PA

4. Payments for claims may be held for 90-days. The Reconciliation Act passed in conjunction with H.R. 3590 allows the Secretary to withhold payments for claims for up to 90-days if it is determined that the submitting supplier poses a high risk for fraud or abuse.

5. Provider Pre-Enrollment Screening and Other Enrollment Requirements. The Act directs the Secretary to develop enrollment screening procedures that will apply to all persons seeking to enroll as new providers or suppliers in the Medicare, Medicaid and CHIP programs. Screening procedures may include licensure checks, criminal background checks, fingerprinting, pre-enrollment site visits, database checks, and such other screening procedures as the Secretary may deem appropriate. The Act also allows

the Secretary to establish enrollment fees for providers and suppliers in these programs. The screening processes will apply to new providers and suppliers, and eventually will apply to existing providers and suppliers upon re-enrollment. The Secretary is also directed to establish processes for enhanced oversight of new providers, to last at least 30 days and up to one year. Such oversight can include prepayment reviews or payment caps, as determined by the Secretary.

The Act also changes the enrollment process by requiring new and re-enrolling providers and suppliers to disclose current or previous affiliations with a provider or supplier that has uncollected debt, has been subject to payment suspensions, or has been excluded from Medicare, Medicaid or CHIP. The Secretary may deny enrollment if he deems the new provider or supplier to pose a risk of program abuse. The Act directs the Secretary to implement the new screening requirements 180 days after the date of enactment.

Comment: Supplier and providers who are contemplating transactions that will involve the enrollment of new entities should anticipate delays in enrollment due to the new screening criteria. It seems likely that other routine transactions, such as re-enrollment, will become more complex and time-consuming, as well.

6. Moratorium of enrollment. The Act also gives the Secretary the authority to impose a temporary moratorium on enrollment of new providers and suppliers, whenever the Secretary determines that a moratorium is necessary to prevent or combat fraud, waste or abuse.

Comment: There is no judicial review available of the Secretary's decision to implement a temporary moratorium. This provision appears to be effective immediately. A moratorium could work a significant hardship on new providers and suppliers, and it is troubling that the Act provides no standards for the imposition of a moratorium and no route for judicial review.

7. Medicaid. Should a supplier be terminated from the Medicare program for submitting false or fraudulent claims, Medicare is required to notify all State Medicaid agencies within 30-days of the date of termination. Suppliers terminated from Medicare are automatically barred from participation in Medicaid.

8. 2014 CPI/U Update Eliminated. A 2% payment increase for product categories included in Round 1 of competitive bidding will be eliminated in 2014.

Comment: As part of the MIPPA legislation to delay competitive bidding and mitigate somewhat the 9.5% reduction to the bid items, the bill allowed for a resumption of the CPI update. *For 2010 through 2013, DMEPOS fee schedules will be increased annually to reflect the CPI-U increase. (In areas where competitive bidding is implemented, the bid contract pricing will apply). In 2014 there will be one additional CPI-U update, as well as an additional 2 percent to those items included in round one and subject to the 9.5 percent cut in 2009.* However, with this reduction, the "pay for" component of the Meek Bill to repeal the program is compromised. The proposed "pay for" is as follows:

The Meek competitive bidding repeal bill proposed to pay for the repeal by:

- In 2010, 2011, and 2012, eliminate the CPI-U updates for all DME, except for group 3 or higher complex rehab, (this CPI-U update was set in the MIPPA 2008), AND reduce all DME payments by 0.25 percentage points.
- In 2013, all DME would receive a CPI-U update.
- In 2014 eliminate the CPI-U for all DME, except for group 3 or higher complex rehab, which would receive a CPI-U update plus 2 percentage points.
- In 2015, All DME, except group 3 or higher complex rehab, would receive no CPI-U update. In 2015, all DME fees would also receive a 0.5 percentage point reduction.
- After 2015, the full CPI-U would be restored.

The net give back for these 5 years is expected to be at least 10%, added to the 9.5% reduction in 2009 gives 19.5%.

9. A yet-to-be defined "productivity adjustment" will lower future consumer price index-urban (CPI-U) updates to the HME fee schedule.

Comment: See above; this may further complicate the "pay for" of the Meek Bill. We believe that this would lower the annual HME update by about one percentage point each year. This provision is not applicable to competitive bidding sites and is applicable to all providers, not just HME providers.

10. A mandatory compliance program will be required for all providers, including HME providers.

Comment: This requirement (under Medicare or Medicaid) to have a mandatory compliance program is extremely broad. Prior to this law, a health care provider or supplier was only required to have a corporate compliance program if it was operating under a Corporate Integrity Agreement or had a contract with the federal government in excess of \$5 million and lasted longer than 120 days. Now, every Medicare or Medicaid supplier or provider must have a corporate compliance program. The requirements for these programs will be set by the Secretary in consultation with that agency's OIG. The PPACA itself only mandates the requirements of compliance programs for only one category of health care provider: skilled nursing facilities. The program has to be "reasonably designed, implemented, and enforced so that it will be generally effective in preventing and detecting criminal, civil and administrative violations under [the PPACA] and in promoting quality of care." In addition, the compliance program is required to have the following elements:

- Established compliance standards and procedures;
- A senior-level compliance officer with sufficient resources and authority;
- Due care to limit discretionary authority to wrongdoers;
- Training and communications;
- A reporting system for employees as well as monitoring and auditing systems;
- Consistent enforcement, including employee discipline;

- Reasonable responses to detected misconduct, including program modifications to prevent further similar offenses; and
- Periodic reassessment of the compliance program.

11. A face-to-face exam will be required for all HME and home health items and services. The Act also requires the face-to-face encounter before the physician (or physician assistant, nurse practitioner, or clinical nurse specialist) may certify the need for home health services and DME, and the Secretary may define the permitted timeframe for such encounters. The face-to-face encounter may be through telehealth technology. The Act's requirements apply to both Medicare and Medicaid. These requirements have an effective date of January 1, 2010.

Comment: Significantly, the Act allows the Secretary to expand the scope of this face-to-face encounter requirement to other items and services covered by Medicare, based upon a finding that such a requirement could reduce the risk of waste, fraud, and abuse. Some, but not all, existing Medicare coverage policies require an encounter between the ordering physician and the patient before a referral can be made. Adding this requirement to two major categories of Medicare benefits is a significant administrative change for the home care industry. As suppliers and providers do not maintain the documentation proving whether and when a face-to-face encounter occurred, this requirement will place more stress on the relationship between home care providers and referring physicians.

12. Recovery Audit Contractor (RAC) program expanded. Section 6411 expands the RAC program, specifically the use of contingency-fee-based RAC contractors, to audit not only Part A and Part B Medicare claims, but also to review Medicare Advantage (Part C), Medicare Prescription Drug (Part D) and Medicaid claims. It also expands the program to Medicaid by December 31, 2010. The RAC program pays contractors on a contingency basis for uncovering overpayments and underpayments to providers.

Comment: This bill is in line with a recent White House Memorandum which states President Obama's support of the use of "high-tech bounty hunters" to help find health care fraud in government-run Medicare and Medicaid programs.

13. Accreditation exemption for certain pharmacies. This provision will exempt from the accreditation requirement pharmacies with less than 5 percent of revenues from Medicare DMEPOS billings until HHS develops pharmacy-specific standards.

14. Additional Documentation and Encounter Requirements for Home Health and Durable Medical Equipment Referrals. Physicians who order durable medical equipment or home health services for Medicare beneficiaries must be enrolled with the Medicare program. Further, the Secretary of Health and Human Services is authorized to extend this recruitment to other items or services under Medicare, including Part D covered drugs. This requirement will become effective July 1, 2010.

Comment: While apparently a simple requirement, this new rule is likely to force home health providers and equipment suppliers to verify the Medicare enrollment of physicians

who order services, which could become a significant administrative burden. Failure to observe their requirement could lead to false claims liability or other sanctions. Until now, it was only necessary to take reasonable steps to verify that physicians ordering services were not excluded from Medicare at the time of the referral. This rule will also put additional burdens on physicians who “opt out” of Medicare, as they will no longer be able to order home health services and durable medical equipment for their Medicare patients.

15. Enhanced Documentation of Referrals for Certain Items or Services, and Encounter Requirements. Physicians, suppliers and providers are required to maintain documentation relating to written orders or requests for payment for durable medical equipment or home health services. Significantly, the Act empowers the Secretary to expand this requirement to other kinds of services covered by Medicare. The Secretary is also empowered to revoke the Medicare enrollment of suppliers and physicians who do not provide access to such documentation on request. This documentation requirement will become part of Medicare provider agreements for all Medicare provider types. The Act expands the Office of the Inspector General’s permissive exclusion authority to exclude entities that fail to provide information relating to the “ordering, referring for furnishing, or certifying the need for” items or services covered by the Medicare and Medicaid programs. This requirement applies to orders, certifications, and referrals made on or after January 1, 2010.

Comment: Congress appears to be concerned that home care orders are not being properly documented and that some portion of the home health services and items currently being paid for by Medicare are not medically necessary.

16. GAO Looks at Competitive Bidding for Manufacturers. While not included in the final version of the health care bill, the Government Accountability Office is studying the viability of such a program. The study was spurred by a request from lawmakers in the House of Representatives who want to determine if competitive bidding for HME manufacturers is feasible for both equipment and services.

Comment: AAHomecare and Invacare recently met with the GAO. The association stressed that product costs are only a small portion of the total cost of furnishing home care products to Medicare beneficiaries and that the "process of moving home medical equipment from the manufacturer to the Medicare beneficiary's home is complex." Said AAHomecare officials: "Both issues would create significant hurdles for an HME manufacturer bidding program and would create serious access-to-care problems."

17. Surety Bonds. The Act gives the Secretary authority to increase surety bond requirements for DME and home health care providers based on the billing volume of the company. Further, it gives the Secretary that latitude to require surety bonds for any other kind of provider or supplier (which could include physicians, IDTFs and hospitals, among others) with a minimum surety bond requirement of \$50,000. The Act does not specify an effective date for the new surety bond requirements, but it appears that implementation will follow rulemaking by the Secretary.

Final Comment: DMEPOS organizations have treated enrollment in the Medicare program almost as an entitlement. Unlike managed care organizations, which have often created limited networks for specialized services, Medicare enrollment is open to any DMEPOS facility that can meet enrollment criteria. The Secretary's new ability to impose a moratorium on enrollment, combined with the mandate to impose new screening criteria, is a move toward restricting enrollment of new DMEPOS organizations in Medicare.

In any case, the enhanced enforcement provisions of this Act put health care providers of all types at greater risk. The disclosure requirements should be of immediate concern, as they require affirmative action.

Fraud-Fighting Provisions of the Health Care Reform Act

While much of the discussion concerning the Health Care Reform Act has addressed private health insurance reforms, there have been significant changes to the Medicare and Medicaid statutes concerning fraud and abuse.

Combined with the creation of the Health Care Fraud Prevention Enforcement Action team, which has already been active in southeastern Michigan and proposed substantial increased budgeting to the Department of Health and Human Services to attack fraud and abuse, it is clear that the next few years will be very active.

The following is a summary of the significant changes. Unless otherwise noted, the effective date of the changes is upon passage of the Act or March 23, 2010.

1. Changes in the Intent Standard for the Anti-Kickback Statute and the Criminal Health Care Fraud Statute, 18 U.S.C. § 1347. Previously, to prove a violation of either statute, the government must show that the defendant acted "knowingly and willfully". Case law has interpreted this standard to require knowledge that the federal statute prohibits the act and engaging in the prohibited conduct with the specific intent to disobey the law.

The Anti-Kickback Statute is amended to provide that a person need not have actual knowledge of the statute or specific intent to commit a violation of the statute. The Health Care Fraud Statute, which covers claims of payment, contains nearly identical amendments.

The specific intent provisions of the prior statutes have served as a deterrent to prosecutors bringing borderline criminal cases resulting in civil recovery actions only. This deterrent has now been removed.

The Anti-Kickback Statute is also amended to provide that claims for items or services resulting from kickback violations are false and fraudulent for purposes of the Civil False Claims Act and the Criminal Health Care Fraud Statute has been amended to provide that violations of the Anti-Kickback Statute are included in the types of conduct that constitute federal health care fraud.

2. Changes to the False Claims Act. Previously, public disclosure was a jurisdictional bar under the False Claims Act unless the individual bringing the suit was the original source of the information. Now, however, courts must dismiss the action brought by relators unless opposed by the government where there has been prior disclosure. The original source tool for relators still exists.

In addition, the disclosure is now limited to criminal, civil or administrative pleadings and reports, hearings, audits or investigations that are federal. For criminal, civil or administrative proceedings for public prior disclosure to apply, the government or its agent must be a party. State disclosures no longer constitute public disclosure.

Disclosure to the news media, however, remains grounds for dismissal.

There is also an expanded definition of original source to include an individual who discloses to the government the information on which the false claims are based prior to the public disclosure and the individual who provides independent knowledge adds materially to the publicly-disclosed information to the government before filing an action.

3. U.S. Sentencing Guidelines. The guidelines are amended to provide an increase between two and four levels for health care offenses involving \$1,000,000 or more.

4. Civil Monetary Penalties. Complementing the federal government's authority under the False Claims Act has been the authority of the Secretary of Health and Human Services to impose civil monetary penalties on persons who engage in various types of unlawful conduct. However, activity under the Civil False Claims Act has far surpassed any actions taken by the Secretary of HHS. The bill expands penalties to include:

- failure to timely provide access for audits, investigations or other statutory functions (up to \$15,000 per day)
- knowingly making or causing to be made a false claim for payment (up to \$50,000 for each claim)
- knowingly making a false statement on an enrollment application (up to \$50,000 for each false statement)
- ordering or prescribing services when the person ordering or prescribing has been excluded (up to \$50,000 for each order or prescription)

The amendments also expand civil monetary penalties to cover the failure to return overpayments.

5. Beneficiary Inducement. As part of HIPAA, civil monetary penalties were authorized for the offering of remuneration to any beneficiary that is likely to influence such individual to order or receive from a particular provider any service payable under Medicare or Medicaid. The bill provides for significant exceptions:

- remuneration that promotes access to care and imposes a low risk of harm to patients and the federal health care programs;
- an offer or transfer of services for free or at less than fair market value for certain coupons, rebates and other rewards from a retailer;
- the offer of services for free or at less than fair market value for certain services not offered as part of an advertisement or solicitation; that are not tied to the provision of other services reimbursed by Medicare or Medicaid; where there is a reasonable connection between the services and medical care of the patient; and where the person

that receives the services is in financial need; and

- effective not earlier than January 1, 2011, the waiver of a prescription drug plan sponsor under Medicare Part D or an MA organization offering an MA-PD plan under Medicare Part C of any co-payment for the first fill of a covered drug that is a generic.

It is interesting that the exception for coupons, rebates or other rewards applies only to retailers and not other entities that offer services to beneficiaries.

6. Penalties for Medicare Advantage or Part D Plans. The bill establishes penalties for Medicare Advantage or Part D plans that misrepresent or falsify information required to be furnished to HHS and for the failure to provide necessary services. The bill further protects beneficiaries from predatory marketing practices such as enrolling individuals in the plan without their consent, transferring an individual from one plan to another solely to generate commissions, and employing or contracting with an individual who engages in conduct for which sanctions can be imposed. The effective date of these amendments is January 1, 2010.

7. Overpayments. Overpayments must be reported and returned within sixty (60) days of identity or the date the corresponding cost report is due. Repayments may be made to the carrier, contractor or intermediary.

An overpayment repaid after the sixty (60) deadline is considered a False Claims Act violation.

The Act further provides for permissive exclusion where providers have failed to return overpayments.

Changes to the Stark Law

1. Self-Disclosure Protocol. The bill establishes a self-disclosure protocol for providers to disclose violations of the Stark law. It authorizes HHS to reduce the amount due and owing for violations of the Stark law to an amount less than that specified in the statute. These protocols are to be established no more than six (6) months from March 23, 2010.

Disclosure of Stark violations has been a major headache to providers in light of the draconian penalties threatened. It remains to be seen if the protocol will make self-disclosure a more viable option.

2. The In-Office Ancillary Services Exception. This is a major change for physicians' offices. The in-office ancillary services exception is the exception commonly used by physicians who order laboratory testing or other diagnostic services. The bill requires that physicians referring MRIs, CTs, and PETs must inform the patients at the time of referral that this service can be obtained by someone other than the referring physician or a physician who is a member of the physician's practice group. The practice must also supply a list of suppliers who furnish such services in the area in which the individual resides. This requirement covers services that are directly supervised by the referring physician or another physician within the physician's practice group. In other words, it covers mobile services where supervision is provided by the ordering doctor's practice. The effective date is January 1, 2010. The bill also gives the Secretary the authority to expand these provisions to other designated health services.

3. Physician-Owned Hospitals. Physician-owned hospitals will no longer be able to participate in the Medicare program unless the physician has an ownership interest and the hospital had a provider number by December 31, 2010. The bill further prohibits the expansion of any existing physician-owned hospitals with very limited exceptions.

Other Miscellaneous Provisions

1. National Provider Identifier. Effective January 1, 2011, all Medicare and Medicaid providers and suppliers must include their National Provider Identifiers and all program applications and claims.

2. Time Limit to Submit Medicare Claims. Claims must be submitted within one (1) calendar year after the date of service for all services furnished after January 1, 2010. For services furnished before January 1, 2010, the submission must be filed not later than December 31, 2010.

3. Increased Disclosure Requirement on Enrollment. Effective one year after enactment, any enrollee that has an affiliation with another provider or supplier that has (i) uncollected debt; (ii) suspension of payments from any federal health care programs; (iii) been excluded from participation in a federal health care program; or (iv) had its billing privileges denied or revoked must disclose this information when submitting an application for enrollment or re-enrollment.

4. Data Sharing. There is no question that the OIG and Department of Justice have shifted their emphasis to data sharing versus reliance on whistleblowers and "street" investigations. The bill contains numerous data sharing provisions, including (i) the establishment of an evidentiary privilege for communications between certain federal and state agencies, including state AG, DOJ, and DHHS; (ii) mandating a federal fraud and abuse collection program for reporting adverse actions; (iii) termination of the health care integrity protection databank and transfer of all data collected to the National Practitioner Databank; (iv) Integrated Data Repository of CMS to include claims and payment data from a variety of programs, including Medicare, Medicaid, Veterans' Affairs, and the health care service with the data from such programs to be matched with the data in the HHS system for identifying fraud; and (v) the National Association of Insurance Commissioners shall develop a model uniform report for federal health insurance companies to assist suspected fraud and abuse with responsible state agencies.

5. Funding. Congress also took steps to insure that enforcement agencies have sufficient financial resources to combat fraud. The Act authorizes \$10,000,000 in increased Health Care Fraud and Abuse Control for each year through 2020 and the Reconciliation Act provides for an additional \$250,000,000 through 2017, beginning with a \$95,000,000 boost in 2011.