Reed Smith Health Care Reform Review

The Patient Protection and Affordable Care Act, as Amended by the Reconciliation Act:

Analysis and Implications for DMEPOS Suppliers

July 2010

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Introduction

Suppliers and manufacturers of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS) will be impacted, directly and indirectly, by numerous provisions of the recently-enacted health reform legislation, H.R. 3590, the Patient Protection and Affordable Care Act (PPACA), as amended by H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), collectively known as the "Affordable Care Act" or ACA.[1]

Among other things, the Affordable Care Act: expands the Medicare DMEPOS competitive bidding program; revises the Medicare DMEPOS fee schedule payments (including applying a "productivity adjustment" to the fee schedule update); exempts pharmacies from certain DMEPOS accreditation requirements; revises Medicare power wheelchair payment policy; mandates disclosure of certain payments between manufacturers and physicians; institutes a variety of new program integrity provisions; and imposes a new tax on medical devices. These provisions are discussed in greater detail below.

This memorandum supplements our extensive Affordable Care Act analysis released in April 2010, which explains how the law expands access to health insurance (including through subsidies, mandates, and market reforms); reduces health care spending (particularly in the Medicare program); expands federal fraud and abuse authorities; and institutes a variety of other health policy reforms.[2] We also have posted additional Reed Smith Health Care Reform Review articles focusing on specific aspects of the legislation on our health policy blog, Health Industry Washington Watch,[3] where we are reporting on implementation efforts associated with the ACA.

Medicare DMEPOS Competitive Bidding Program Provisions

By way of background, under the Medicare DMEPOS competitive bidding program, only suppliers who are successful bidders will be eligible to furnish certain categories of DMEPOS to Medicare beneficiaries in certain geographic areas (with very limited exception). Successful bidders will be paid based on the median of the winning suppliers' bids for each of the selected items in the region, rather than on the Medicare fee schedule or supplier bid amount. Competitive bidding is being phased in geographically and by product category.

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[1] The text of the PPACA is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf. The text of the Reconciliation Act is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4872enr.txt.pdf.

[2] Our major analysis of the legislation is available on our website at http://www.reedsmith.com/publications/white_papers.cfm?cit_id=27700&widCall1=customWidgets.content_view_1&usecache=false.

[3] See http://www.healthindustrywashingtonwatch.com/articles/ppaca-implementation/.

The Centers for Medicare & Medicaid Services (CMS) conducted the first round of DMEPOS competitive bidding in 2007 in 10 geographic areas and for 10 product categories, and the program briefly went into effect in July 2008. Because of widespread concerns about how the program was implemented, however, the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) blocked round 1 and adopted a series of changes to the program. Under MIPPA, CMS was directed to conduct a new round 1 rebid in nine geographic areas in 2009, and conduct a second phase of bidding in 2011 in "an additional 70" of the largest metropolitan statistical areas (MSAs). The delay was financed by cutting fee schedule payments for items included in round one by 9.5% nationwide beginning January 1, 2009, followed by a scheduled 2% increase in 2014 (with certain exceptions). CMS conducted the round 1 rebid last year, and on July 2, 2010, CMS announced that Medicare reimbursement for items included in the round 1 rebid will be reduced an average of 32 percent compared to fee schedule amounts. CMS is expected to announce winning bidders later this year, with contract prices set to go into effect January 1, 2011.

Section 6410 of the PPACA requires the Secretary of Health and Human Services (the Secretary) to expand the number of areas to be included in round 2 of the competitive bidding program from 79 to 100 of the largest MSAs. In addition, the PPACA requires (rather than permits) the Secretary to use information regarding payments determined under competitive bidding to adjust DMEPOS payments in areas outside of competitive bidding areas beginning in 2016. Likewise, for items furnished on or after January 1, 2016, the Secretary is directed to continue to adjust prices as additional information is obtained when new items are subject to competitive bidding, or when contracts are recompeted. Thus the PPACA magnifies the impact of the DMEPOS competitive bidding program on suppliers outside of competitive bidding areas, enhancing the importance of close monitoring of implementation of this program by all DMEPOS suppliers and manufacturers.[4]

On July 13, 2010, CMS is publishing its proposed Medicare physician fee schedule update for calendar year 2011, which incorporates a number of revisions to DMEPOS policy, including identification of the expanded round 2 competitive bidding MSAs.[5]

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[4] For detailed background information regarding the DMEPOS competitive bidding program, see http://www.reedsmith.com/_db/_documents/hc0804.pdf. For Reed Smith's ongoing reporting on this issue, see http://www.healthindustrywashingtonwatch.com/tags/dmepos-competitive-bidding/.

[5] See http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?itemID=CMS1236707.

Other Medicare DMEPOS Reimbursement Provisions

Revision of Market Basket Updates, Incorporation of Additional Productivity Adjustments

Section 3401 of the PPACA eliminates the full inflation update to the DME fee schedule for 2011 through 2014. It also eliminates the 2% add-on discussed above that was scheduled to be applied in 2014 to those items that had been selected for inclusion in the first round of the DMEPOS competitive bidding program and that had been subject to a 9.5% fee schedule reduction in 2009.

Instead, for 2011 and each subsequent year, Medicare fee schedule amounts for DMEPOS and certain other Part B items[6] will be increased by the rate of increase in the Consumer Price Index for All Urban Consumers (CPI-U), less a "productivity adjustment" intended to reflect productivity gains in delivering health care services and to encourage more efficient care.[7] This productivity adjustment – which essentially is a rate cut – also is being applied to payment updates for a variety of other types of Medicare providers. For each provider type, the productivity offset equals a 10-year average of a statistic that is published by the Bureau of Labor Statistics (BLS), specifically, the "percentage change in the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity"[8] as projected by the Secretary for the applicable 10-year period. Using the average change in the applicable productivity measures from 1999-2008, the offset percentage would be approximately 1.3%[9], although it is important to note that because the productivity offset is equal to a 10-year moving average, it will change from year-to-year. Moreover, the ACA specifies that the application of the productivity adjustment may result in a payment rate for a year being less than the payment rate for the previous year (i.e., if the amount of the productivity adjustment exceeds the amount of the inflation update).

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[6] Specifically, this provision applies to DME, prosthetic devices, orthotics, and prosthetics, and to the update for any fee schedule established for medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine.

[7] Note that in a December 10, 2009 analysis of an earlier House health reform bill, the CMS Office of the Actuary (OACT) warned that estimated savings associated with annual productivity adjustments for most Medicare providers are probably "unrealistic" since it is doubtful most providers could reduce costs to the extent envisioned in the legislation.

[8] The BLS defines multi-factor productivity (MFP) as follows: "MFP measures reflect output per unit of a set of combined inputs. A change in MFP reflects the change in output that cannot be accounted for by the change in combined inputs. As a result, MFP measures reflect the joint effects of many factors including research and development (R&D), new technologies, economies of scale, managerial skill, and changes in the organization of production."

[9] This calculation is based on numbers published by the BLS and available at www.bls.gov.

Medicare Payment for Power-Driven Wheelchairs

Medicare suppliers have long been required to give beneficiaries the option of obtaining power wheelchairs on a lump sum purchase basis at the time the wheelchair is furnished, or on a capped rental basis.[10] Section 3136 of the PPACA eliminates the lump-sum payment option for power-driven wheelchairs, although the lump-sum payment option is maintained for complex, rehabilitative power wheelchairs.

The PPACA also modifies rental payment amounts for power-driven wheelchairs. Specifically, payment is set at 15% (rather than 10%) of the purchase price for each of the first three months, and at 6% (rather than 7.5%) of the purchase price for each of the remaining 10 months.

These provisions are effective for power-driven wheelchairs furnished on or after January 1, 2011, except that they will not apply to payment made for items and services furnished under DMEPOS competitive bidding contracts entered into prior to January 1, 2011.[11]

Independent Payment Advisory Board

In the longer term, DMEPOS reimbursement policy could be impacted by the recommendations of a new Independent Payment Advisory Board (IPAB) established under sections 3403 and 10320 of the PPACA. The legislation charges the IPAB with developing and submitting proposals to Congress and the President to reduce Medicare per-capita spending when projected spending growth exceeds a target. In contrast to the recommendations of the current Medicare Payment Advisory Commission (MedPAC), whose recommendations are purely advisory, the IPAB's proposals will go into effect automatically unless Congress enacts specific legislation with alternative provisions to achieve the required level of savings (with certain exceptions).[12] Such legislation would be considered under complex "fast track" parliamentary procedures.

The IPAB's first proposal with savings recommendations could be submitted by January 14, 2014, for implementation in 2015, if the Medicare per-capita target growth rate is exceeded. For 2014 through 2017, this target rate is based on a comparison of the projected rate of growth in Medicare spending per beneficiary, compared with the average of the increase in the CPI-U and CPI for medical care (CPI-M); in subsequent years proposals will be required only when the

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[10] Under the Deficit Reduction Act of DRA of 2005, suppliers must transfer title to the equipment to the beneficiary on the first day after the 13th continuous month of use during which payment is made for the item.

[11] The proposed Medicare physician fee schedule rule for CY 2011 would implement the new power wheelchair policy. See http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?itemID=CMS1236707

[12] Note that in addition to the binding recommendations triggered by specific spending growth levels, the IPAB is authorized to submit nonbinding recommendations for years with lower growth rates. The Board also is authorized to submit non-binding recommendations to Congress and the President on ways to slow the growth in national, non-federal health care spending.

projected rate of growth in Medicare spending exceeds the increase in the per-capita gross domestic product plus 1%. Any required IPAB proposals must achieve specified levels of savings, ranging from the lesser of (1) 0.5% to 1.5%, and (2) the amount by which Medicare spending exceeds the trigger.

With regard to the Medicare payment reduction options the IPAB can consider, the PPACA prohibits the board from making proposals that ration care, raise taxes or Part B premiums, or change Medicare standards for benefits, eligibility, or cost-sharing. The IPAB also is precluded from submitting proposals that reduce Medicare payments prior to December 31, 2019, for providers scheduled to receive a reduction in their payment updates in excess of a reduction because of productivity. The IPAB also is directed, as feasible, to: (1) prioritize recommendations that would extend Medicare solvency; (2) include recommendations that improve the health care delivery system and health outcomes (such as by promoting integrated care, care coordination, prevention and wellness efforts, and quality and efficiency improvement), and protect beneficiary access to "necessary and evidence-based items and services," including in rural and frontier areas; (3) target reductions to sources of excess Medicare cost growth; (4) consider the effects on Medicare beneficiaries of changes in provider and supplier payments; (5) consider the effects of proposals on providers with actual or projected negative profit margins or payment updates; (6) consider the unique needs of individuals dually eligible for Medicare and Medicaid; and (7) consider the IPAB's findings on system-wide health care costs, access, and quality in developing proposals that effectively promote the delivery of efficient, high-quality care to Medicare beneficiaries. Any such proposals may not increase Medicare spending over the initial 10-year period.

The Congressional Budget Office (CBO) expects this provision to yield savings of about $28 billion over the period of 2015 to 2019.[13] The CMS OACT predicted that most of the savings from this provision would be generated as a result in reductions in payments to physicians, hospitals, Medicare Advantage plans, and Part D drug plans.[14] It is too early to predict the extent to which IPAB's future recommendations will impact DMEPOS suppliers, or the extent to which Congress will act to substitute its own savings plans for those of the IPAB.

[13] See http://www.cbo.gov/doc.cfm?index=10868&type=1, page 11.
[14] See http://src.senate.gov/files/OACTMemorandumonFinancialImpactofPPAA%28HR3590%29%2812-10-09%29.pdf, page 10.

Exemption of Certain Pharmacies from DMEPOS Accreditation Rules

MIPPA established a statutory requirement that Medicare DMEPOS suppliers be accredited as meeting certain quality standards in order to furnish DMEPOS items and services on or after October 1, 2009 (with limited exceptions for certain health care professionals).[15]

Section 3109 of the PPACA exempts all pharmacies from the DMEPOS accreditation requirements until January 1, 2011. Moreover, with respect to DMEPOS items furnished on or after January 1, 2011, the PPACA exempts certain pharmacies from the DMEPOS accreditation requirements until such time as the Secretary develops an "alternative accreditation requirement" that the Secretary determines is "more appropriate for such pharmacies." In order to qualify for this provision, the pharmacy must:

- Have billings for such DMEPOS items totaling less than 5% of total pharmacy sales[16];
- Have been enrolled as a DMEPOS supplier for at least five years and have had no final adverse action imposed in the past five years;
- Submit to the Secretary an attestation (in the manner and at the time specified by the Secretary) that it meets the alternative accreditation criteria; and
- Agree to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the criteria are met (including a certification by an accountant on behalf of the pharmacy or submission of the pharmacy's tax returns for the relevant period, as requested by the Secretary).

Note that this provision does not affect the requirement for pharmacies to be accredited as a condition of participating in the DMEPOS competitive bidding program.

Comparative Clinical Effectiveness Research/PCORI

Section 6301 of the PPACA establishes a private, nonprofit corporation to be called the Patient–Centered Outcomes Research Institute (PCORI or Institute) to identify national priorities for comparative effectiveness research, taking into account, among other factors, disease incidence, burden, gaps in clinical evidence, and "the effect on national expenditures" of a health care treatment strategy.[17] The research to be pursued is completely open-ended and will include studies to measure the comparative clinical effectiveness, risks and benefits of: health care

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[15] A CMS fact sheet regarding this provision is available at http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccExemptForCertainPharmaciesFactSheet.pdf. For additional information on DMEPOS accreditation requirements, see http://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOSAccreditation.asp.

[16] The level of total pharmacy sales is to be determined based on average total pharmacy sales for the previous three calendar years, three fiscal years, or other yearly period specified by the Secretary.

[17] Section 6302 terminates the prior authority to create the "Federal Coordinating Council for Comparative Effectiveness Research" contained in the American Recovery and Reinvestment Act of 2009.

interventions, treatment protocols, medical devices, drugs, biologics, and any other treatments or strategies being used in prevention, diagnosis or management of illness and injury. The Institute's work will be transparent, with the public afforded an opportunity to comment on the research agenda, as well as on published reports of research. In addition, CMS may use the research findings of the Institute in making coverage decisions only through a transparent process that includes public comment. The Institute will carry out the comparative effectiveness research agenda through contracts with existing federal agencies, academic research centers, and the private sector.

While DMEPOS items are not expected to be an early priority for the PCORI, selected items – particularly those that are more costly or that are one of several treatment options for particular medical conditions – could be candidates for comparative effectiveness research. Accordingly, DMEPOS suppliers and manufacturers should continue to monitor developments in this area, particularly as the research agenda is being established.[18]

Reporting of Manufacturer Payments to Physicians

Section 6002 of the PPACA incorporates many of the provisions of the Physician Payment Sunshine Act that Sen. Charles Grassley (R-Iowa) introduced several years ago to encourage greater transparency in the relationships between drug and device companies and physicians.

Beginning March 31, 2013, and annually thereafter, any manufacturer of a covered drug, device, biological or medical supply[19] that provides a payment or other transfer of value to a "covered recipient" – a physician or a teaching hospital – must submit to the Secretary, in electronic form, the following information:

- The covered recipient's name and business address[20];
- If a physician, the physician's specialty and national provider identifier;
- The amount of the payment or other transfer of value, and the dates on which it was provided to the covered recipient;
- A description of the form of the payment or other transfer of value (e.g., cash or cash equivalent, in-kind items or services, stock or stock options);
- A description of the nature of the payment or other transfer of value (e.g., consulting fees, honoraria, gift, entertainment, food, travel, education, research, charitable contribution);

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[18] Note that in the first step toward implementation of this provision, the Government Accountability Office has solicited nominations for the PCORI Governing Board. See http://edocket.access.gpo.gov/2010/pdf/2010-10826.pdf.

[19] A "covered drug, device, biological, or medical supply" is any product for which payment is available under a federal health care program, such as Medicare or Medicaid.

[20] If a manufacturer provides a payment or other transfer of value to an entity or individual *at the request of or designated on behalf of* a covered recipient, the manufacturer must disclose that payment or other transfer of value under the name of the covered recipient.

- If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of such drug, device, biological, or medical supply; and
- Any other categories of information that the Secretary determines to be appropriate.

In addition, the PPACA requires manufacturers and group purchasing organizations (GPOs) that purchase, arrange for, or negotiate the purchase of covered products, to submit to the Secretary certain information regarding ownership or investment interests held by a physician (or an immediate family member of the physician) in the manufacturer or GPO during the preceding year.[21]

Not later than October 11, 2011, the Secretary shall establish procedures for manufacturers and GPOs to submit information to the Secretary, and for the Secretary to make such information available to the public. Beginning September 30, 2013, and on June 30 of each year thereafter, the Secretary is to make all payment, ownership interest, and enforcement information publicly available on a searchable website. Note, however, that the PPACA provides for delayed publication of payments made under product research or development agreements, and for clinical investigations.[22]

The definition of "payment or other transfer of value" does not include the following, and as such, these items do not need to be reported to the Secretary:

- Payments or transfers of value of less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the manufacturer during the calendar year exceeds $100 (adjusted annually for inflation);
- Product samples that are not intended to be sold and are intended for patient use;
- Educational materials that directly benefit patients or are intended for patient use;
- Loans of a covered device for a short-term trial period, not to exceed 90 days;
- Items or services provided under a contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device;
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in his or her professional capacity;
- Discounts and rebates;
- In-kind items used for the provision of charity care;

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[21] This reporting requirement does not apply to physician's ownership or investment interest in a publicly-traded security or mutual fund.

[22] Specifically, for payments or other transfers of value made to covered recipients under product research or development agreements for services furnished in connection with research on a potential new medical technology, or a new application of an existing technology, or the development of a new drug, device, biological, or medical supply, or in connection with a clinical investigation of a new drug, device, biological, or medical supply, information will not be made available to the public until the earlier of the following: the date of FDA approval or clearance of the product; or four calendar years after the date such payment or other transfer of value is made.

- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund;
- In the case of a manufacturer that offers a self-insured plan, payments for the provision of health care to employees under the plan;
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional; and
- Compensation paid by a manufacturer to a covered recipient who is directly employed by and works solely for that manufacturer or distributor.

The penalties for failure to report include civil monetary penalties of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest that is not reported (not to exceed $150,000). A "knowing" failure to report will result in even higher penalties. Funds collected by the Secretary as a result of the imposition of a civil monetary penalty will be used to carry out this law.

Effective January 1, 2012, this law will preempt any state laws that require a manufacturer to disclose or report the type of information described above regarding payments or other transfers of value made to covered recipients. However, the law will *not* preempt any state laws that require the disclosure or reporting of information that falls outside of the scope of the above requirements.[23]

Program Integrity Provisions

In keeping with the federal government's close scrutiny of fraud and abuse within the DME industry in recent years, the Affordable Care Act includes a number of program integrity provisions aimed specifically at DMEPOS suppliers. For instance, physicians must document a face-to-face encounter with a beneficiary during the six-month period preceding a written order for any DME; the Secretary may disenroll for up to one year a Medicare supplier that fails to maintain and provide access to written orders for DME; and the Secretary must establish procedures for screening Medicare and Medicaid providers. These provisions are discussed

[23] Currently, five states – Maine, Massachusetts, Minnesota, Vermont and West Virginia, as well as the District of Columbia – have enacted unique laws regarding the financial arrangements between drug and/or device companies and health care professionals. Other states, such as California and Nevada, require companies to adopt a marketing code of conduct, which is not addressed in the PPACA. Companies therefore will have to continue to report certain expenditures and make compliance certifications to state authorities. In addition, the new law applies only to payments or other transfers of value to physicians and teaching hospitals, whereas many state laws cover payments made to a broad range of individuals and entities, including hospitals, nursing homes, pharmacists, and all individuals authorized to prescribe, dispense, or purchase prescription drugs or medical devices. In addition, while under the federal law many items are exempt from the reporting requirements, such as loans of medical devices and charitable contributions, some states, such as Vermont, require that these types of interactions with covered recipients be disclosed.

below. Note that DMEPOS suppliers, like other health providers, also may be impacted by broader expansion of fraud and abuse authorities included in the Affordable Care Act, including changes to the federal False Claims Act (FCA), the Anti-Kickback Statute, and the Civil Monetary Penalty laws. These provisions are discussed in greater detail in a separate Reed Smith Health Care Reform Review analysis.[24]

Provider Screening and Other Enrollment Requirements under Federal Health Programs

Section 6401 of the PPACA requires the Secretary, in consultation with the Office of Inspector General (OIG), to establish procedures for screening providers and suppliers participating in federal health care programs (specifically, Medicare, Medicaid, and CHIP). The Secretary has authority to set different levels of screening depending upon the type of provider or supplier. At a minimum, all providers and suppliers will be subject to licensure checks, and additional screening items could include fingerprinting, criminal background checks, multi-state database inquiries, and surveys/site visits. An application fee of $200 for individual practitioners and $500 for institutional providers and suppliers will be imposed to cover the costs of screening each time they re-verify their enrollment (every five years).[25] This section also provides for provisional enrollment for new providers and suppliers, during which CMS could impose pre-payment review and payment caps.

Additionally, this section requires new enrollees in Medicare, Medicaid or CHIP to disclose current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a federal health care program, or has had their billing privileges revoked. It also requires the Secretary, in consultation with the OIG, to require certain providers and suppliers to have mandatory compliance programs. Implementation and other details will be determined by later regulation.

Note that while these provisions are intended to address rising enrollment fraud, especially among suppliers, they (like other of the ACA's program integrity provisions) are likely to cause a significant administrative burden among law-abiding providers and suppliers.

Physicians Who Order DME, Other Services, Must Be Medicare-Enrolled, Maintain Documentation

Section 6405 of the PPACA provides that physicians who prescribe DME or home health services must be enrolled in the Medicare program. This requirement could be extended by regulation to other services.

In addition, section 6406 authorizes the Secretary to disenroll for up to one year a Medicare-enrolled physician or supplier that fails to maintain and provide access to written orders or

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[24] Available at http://www.reedsmith.com/_functions/download.cfm?use_id=0&fde_id=10319.

[25] PPACA section 10603 removes the enrollment fee for physicians.

requests for payment for DME, certification for home health services, or referrals for other items and services, effective January 1, 2010. A requirement to maintain and provide access to such documentation also is added to the general Medicare provider enrollment requirements set forth at section 1866 of the SSA. Moreover, the PPACA extends the OIG's permissive exclusion authority to include individuals or entities that order, refer, or certify the need for health care services, but that fail to provide adequate documentation to verify payment.

On May 5, 2010, CMS published an interim final rule with comment period implementing several enrollment and documentation changes to the Medicare and Medicaid programs as mandated by the PPACA.[26] In the final rule, CMS requires providers and suppliers to include their National Provider Identifier (NPI) on all Medicare enrollment applications, as well as on all claims submitted to the Medicare and Medicaid programs. In addition, Part B services must be ordered or referred by a physician or, when permitted, by another eligible professional.[27] The final rule also requires physicians and other eligible professionals who order or refer Part B services for Medicare beneficiaries to be enrolled in the Medicare program or maintain a valid opt-out record. All claims submitted for Part B items or services must contain the legal name and NPI of the physician or eligible professional who ordered or referred the item or service. In addition, the rule requires both the furnishing and ordering provider or supplier of DMEPOS, home health, laboratory, imaging, or specialist services to maintain documentation of the order or referral for seven years (including the NPI of the ordering or referring physician or eligible professional), and to supply this documentation to CMS or the Medicare contractor upon request. Failure to comply with the documentation requirements may result in a one-year revocation of Medicare enrollment and billing privileges. Although much of the final rule was mandated by the PPACA, CMS is using its discretion to expand ordering and referring requirements to all Part B items and services, except prescribed drugs.[28]

Requirement for Face-to-Face Encounter with Patient Before Physicians May Certify Eligibility for DME

Section 6407 of the PPACA provides that as a condition of a written order for DME under Medicare, the physicians must document that the physician, physician assistant, nurse practitioner, or clinical nurse specialist has had a face-to-face encounter (including through

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[26] See http://edocket.access.gpo.gov/2010/pdf/2010-10505.pdf. The rule is effective July 6, 2010, and comments will be accepted through the effective date.

[27] With respect to home health services, the services must be ordered by a physician (not an "eligible professional").

[28] In the preamble to the final rule, CMS indicates that it "reserves the right" to apply these enrollment and ordering requirements to Part B drugs within the next year.

telehealth, as permitted) with the beneficiary during the six-month period preceding the written order, or other reasonable timeframe as determined by the Secretary.[29]

The PPACA also establishes a requirement that physicians document face-to-face encounters with beneficiaries prior to issuing a certification for home health services. Likewise, the Secretary is 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. Given that in its May 5, 2010 rule implementing several PPACA enrollment and documentation changes, CMS adopted a broad interpretation of similar authority to expand certain ordering and referring requirements to most Part B items and services, CMS likewise can be expected to apply the face-to-face encounter requirement to additional types of providers.

90-Day Period of Enhanced Oversight for Initial Claims of DME Suppliers

Section 1304 of the Reconciliation Act authorizes the Secretary to hold Medicare claims for up to 90 days for certain new DME suppliers. Specifically, effective January 1, 2011, if the Secretary determines that there is a significant fraud risk among suppliers furnishing certain types of DME or operating in certain geographic areas, the Secretary can withhold Medicare payment to such suppliers for 90 days after the date the supplier first submits a DME claim. According to a House Rules Committee analysis, this period would enable enhanced oversight of such claims.

Surety Bonds for DMEPOS Suppliers

As of October 2, 2009, most Medicare-enrolled DMEPOS suppliers are required to submit a valid surety bond to CMS's contractor, the National Supplier Clearinghouse, subject to certain limited exceptions. Specifically, suppliers are required to post a $50,000 surety bond from an authorized surety, unless (1) the supplier is a high-risk supplier (e.g., has had a supplier number revoked, a license suspended, felony conviction, or health program exclusion within 10 years), in which case the bond amount will be increased, or (2) the supplier qualifies for an exemption from the surety bond requirement (e.g., certain physicians and nonphysician practitioners, certain state-licensed orthotic and prosthetic personnel, and suppliers operated by a federal, state, local, or tribal government agency if bonded under state law).[30]

Section 6402 of the PPACA requires that the Secretary take into account the volume of billing for a DME supplier or home health agency[31] when determining the size of the surety bond. The

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[29] Under the authority of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS already requires a face-to-face examination of a beneficiary as a condition for Medicare payment of power mobility device claims.

[30] See 74 *Fed. Reg*. 165 (Jan. 2, 2009).

[31] Although CMS issued regulations to establish surety bond requirements for home health agencies (see 42 C.F.R. 489.60 *et seq.*), those requirements currently are not being enforced.

Secretary also can impose this requirement on other providers and suppliers, depending on the associated level of risk presented.

Other Enhanced Medicare and Medicaid Program Integrity Provisions

The Affordable Care Act includes a variety of provisions designed to enhance Medicare and Medicaid program integrity efforts, including the following of particular interest to suppliers:

- **Reporting and Returning Overpayments**: Section 6402 of the PPACA requires that overpayments be reported and returned within 60 days from the date of identification or by the date that the corresponding cost report is due (as applicable). In addition, the provision specifically ties such overpayments to the "retention of overpayments" language in the federal FCA.[32]
- **Payment Suspensions.** Section 6402 of the PPACA allows the Secretary to suspend payments to a provider or supplier pending a fraud investigation.
- **Maximum Period for Submission of Medicare Claims.** Section 6404 of the PPACA provides that beginning January 2010, the maximum period for submission of any Medicare claim is reduced to not more than 12 months from the date of service.
- **Elimination of Medicare Prepayment Medical Review Limitations.** Section 1302 of the Reconciliation Act repeals section 1874a(h) of the Social Security Act, which had required prepayment reviews to be conducted under certain protocols, and which limited "non-random" prepayment reviews unless there was a likelihood of sustained or high-level of payment error. Thus under this provision, these provider and supplier protections against random governmental audit and review have been eliminated.

Medical Device Excise Tax

The Affordable Care Act imposes fees or taxes on a number of health industry segments to help offset the costs associated with insurance coverage expansion and other provisions of the Act. The fees associated with the medical device industry went through significant revision during the legislative process. As originally approved in the PPACA (but subsequently amended), an annual fee would have been imposed on medical device manufacturers totaling $2 billion for the years 2011 through 2017 and $3 billion for years after 2017, based on market share. The fee would not have applied to companies with sales of medical devices in the U.S. of $5 million or less, nor would it have applied to any sale of a Class I product or any sale of a Class II product that is primarily sold to consumers at retail for not more than $100 per unit.

[32] For additional analysis regarding this section, see our Reed Smith Health Care Reform Review: Analysis and Implications of Fraud Abuse and Program Integrity Provisions.

Note, however, that section 1405 the Reconciliation Act repealed the PPACA version of the device fee, and instead imposes a 2.3% excise tax on taxable medical device sales by manufacturers, producers, and importers, effective for sales on or after January 1, 2013. "Taxable medical devices" generally include devices intended for human use, except for (1) eyeglasses, (2) contact lenses, (3) hearing aids, and (4) other devices determined by the Secretary of the Treasury to be purchased by the general public at retail for individual use.[33] Questions already have arisen regarding particular items that may or may not be exempted under the retail device exemption to the excise tax. The Treasury Department has not yet issued guidance addressing this and other related implementation issues, although we expect such guidance will be issued well before the 2013 implementation date.

Conclusion

DMEPOS suppliers participating in the Medicare program have faced numerous challenges in recent years, including rate cuts, competitive bidding, accreditation and surety bond requirements, and heightened federal enforcement efforts. The Affordable Care Act continues this trend, imposing new reimbursement cuts and an excise tax, while in many cases increasing the costs associated with participating in the Medicare program.

We note that suppliers and manufacturers also could be impacted by numerous other provisions of the Affordable Care Act not addressed in this analysis, including provisions expanding insurance access, targeting quality and public health improvements, and expanding fraud and abuse authorities, among many others. We therefore encourage our clients to review our broader overview of the Affordable Care Act, along with other targeted Reed Smith Health Care Reform Review articles focusing on specific aspects of the legislation. These publications are available on our health policy blog, Health Industry Washington Watch,[34] where we also are reporting on ongoing implementation efforts associated with the ACA. We look forward to working with our clients to develop and implement strategies to respond to enactment of the Affordable Care Act, and we would be pleased to answer any questions you have about the new law or its impact.

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[33] Note that an earlier version of the Reconciliation Act would have exempted Class I medical devices from this tax, but the final version did not include an exemption for Class I devices.

[34] See http://www.healthindustrywashingtonwatch.com/articles/ppaca-implementation/.