

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID PROVIDER
ENROLLMENT STANDARDS:
MEDICAL EQUIPMENT PROVIDERS**



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OBJECTIVE

To (1) identify the standards used by selected States to enroll Medicaid durable medical equipment (DME) providers, (2) determine the extent to which States verify that providers meet these standards, and (3) determine the extent to which States reenroll Medicaid DME providers.

BACKGROUND

The Office of Inspector General has previously identified concerns about fraudulent DME providers in the Medicare program. Similarly, the Government Accountability Office has also determined that vulnerabilities exist for ensuring the integrity of Medicaid providers. Provider enrollment standards represent one mechanism States can use to protect the integrity of their Medicaid DME programs.

States are mandated to provide certain basic services to recipients of Medicaid home health services. These include medical supplies, equipment, and appliances, which are often referred to as DME. States enroll providers to supply DME to Medicaid beneficiaries, and assign providers identification numbers entitling them to receive reimbursements under the State's Medicaid program.

Each State sets its own standards (defined in this report as any safeguards, guidelines, requirements, or practices) for the enrollment of Medicaid DME providers. In addition, States may verify whether providers meet standards at initial enrollment, and may also review providers after enrollment, to determine whether providers continue to adhere to State standards. One method of verifying whether a DME provider meets State standards is to conduct site visits of the provider's location.

Unlike Medicaid, Medicare has provider enrollment standards that are uniform across all States (except licensure requirements that vary from State to State). Compliance with most of these standards is verified by the National Supplier Clearinghouse (NSC) through site visits, while compliance with other standards is verified when the application is reviewed. In addition to initial enrollment, Medicare also requires providers to reenroll every 3 years, during which time providers must certify they meet and will continue to meet Medicare standards.

There are planned changes for DME provider enrollment in the Medicare program. In August 2006, CMS issued a final rule requiring

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DME suppliers to go through an accreditation process. This process will utilize approved quality standards that DME suppliers must meet to participate in and bill the Medicare program. Until these changes are fully implemented, NSC will continue with its enrollment responsibilities, which include conducting site visits and reenrolling DME providers.

Providers may enroll in both the Medicare and Medicaid programs. If providers are enrolled in both programs, they are subject to both the Medicare standards as well as State provider enrollment standards. There are no estimates currently available for the number of providers dually enrolled.

To address the three objectives of our evaluation, we collected data from 14 States and the District of Columbia (referred to as 15 States throughout the report) using e-mail and telephone surveys. We also examined States' provider enrollment applications and written documentation about State standards to conduct a selective review of State-reported information. Our data collection was completed during September and October 2005.

FINDINGS

States that we reviewed employed a variety of standards for DME provider enrollment. All 15 States in our evaluation reported various DME provider enrollment standards. The goal of some of these standards, such as providers posting a sign and hours of operation, help ensure that an appropriate physical facility is being operated. In addition, standards include licensure of providers and obtaining surety bonds. One State imposed a moratorium for enrollment of new DME providers.

Seven of the fifteen States required providers to enroll as Medicare DME providers, which subjects all Medicaid providers in these seven States to Medicare standards. The eight remaining States did not require providers to be enrolled in the Medicare DME program. For these eight States, data regarding how many Medicaid DME providers choose to enroll as Medicare DME providers (and, therefore would be subject to Medicare standards) are not available.

Most States that we reviewed were not routinely verifying whether providers met all State DME provider enrollment standards. While the States in our review requested information from providers during the enrollment process, most of these States were not routinely verifying all of the information submitted by providers. For example, while all 15 States requested that applicants disclose their criminal history, only 2 States routinely conducted criminal background checks at enrollment. Florida and New York were the only States in our review that verified whether providers met all of their reported standards.

Seven of the fifteen States did not conduct routine site visits at enrollment; however, four of these seven States did require Medicare enrollment as a condition of Medicaid enrollment. By requiring Medicare enrollment, applicants should receive site visits by NSC in order to enroll in the Medicare program. The remaining three States neither performed routine site visits to verify enrollment information nor required Medicare DME participation as a condition of enrollment.

Four of the fifteen States routinely reenrolled DME providers; two additional States reported recent initiatives to reenroll providers.

For the four States that routinely reenrolled providers, the timeframe for reenrollment varied from 2 to approximately every 5 years. One of the 2 States that reported recent reenrollment initiatives, California, reported that 646 of its 1,420 DME providers voluntarily chose to leave the program during 1999 through 2004. The other State, New Jersey, was reenrolling all providers for the first time; this process is expected to continue during 2006.

Nine States did not conduct Medicaid reenrollment. However, five of these nine States did require that the provider be enrolled in the Medicare program. For Medicare reenrollment, providers must certify every 3 years that they meet Medicare standards and should receive site visits as part of the Medicare reenrollment process. In contrast, the remaining four States neither routinely reenrolled DME providers nor required that providers be enrolled in Medicare.

CONCLUSION

Our review determined that the 15 States reviewed employed a variety of provider enrollment standards to protect their Medicaid DME programs. Some of these standards, such as providers posting a sign and hours of operation, help ensure that an appropriate physical facility is being operated. Also, standards include licensure of providers and

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obtaining surety bonds. In addition, seven of the States that we reviewed also required Medicaid providers to enroll as providers in the Medicare program, which subjects Medicaid providers in these States to Medicare standards.

Despite the presence of these standards, we determined that most of the 15 States were not verifying whether providers met all provider enrollment standards, and that 7 of the 15 States were not conducting routine site visits at initial enrollment. In addition, only 6 of the 15 States reported that they either routinely reenrolled providers, or had recent initiatives to reenroll providers.

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OBJECTIVE

To (1) identify the standards used by selected States to enroll Medicaid durable medical equipment (DME) providers, (2) determine the extent to which States verify that providers meet these standards, and (3) determine the extent to which States reenroll Medicaid DME providers.

BACKGROUND

The Office of Inspector General (OIG) has previously highlighted concerns about fraudulent DME providers in the Medicare program.¹ Similarly, the Government Accountability Office (GAO) has also determined that vulnerabilities exist for ensuring the integrity of Medicaid providers.² A 2004 GAO report advised that preventing high risk providers, intent on fraudulently billing, from entering the Medicaid program is more efficient than attempting recovery of payments once they have been made.³ Provider enrollment standards represent one mechanism States can use to protect the integrity of their Medicaid DME programs.

Durable Medical Equipment, Supplies, and Appliances

States are mandated to provide certain basic services to recipients of Medicaid home health services. These include the provision of medical supplies, equipment, and appliances,⁴ which are often referred to as DME. DME includes many different types of devices, such as wheelchairs, oxygen equipment, diabetic equipment, and canes. Federal regulations do not define DME for Medicaid, and each State decides what equipment to cover. In addition, States may offer other devices, such as prosthetics, at their discretion.⁵ The Centers for Medicare & Medicaid Services (CMS) does not estimate expenditures specifically for Medicaid DME.

Enrollment of Medicaid DME Providers

Federal Requirements. At enrollment, Medicaid providers are required to disclose information regarding ownership and control of the DME business.⁶ In addition, providers must disclose whether individuals with ownership and control of, or management or other similar responsibilities for, the DME provider have been convicted of any criminal offense relating to the Medicare or Medicaid program.⁷ Providers must also disclose if an individual with ownership or management responsibilities has had civil or monetary penalties

imposed relating to health care programs, and if such a person has been excluded from participation in Medicare or any State health care program.⁸ States must notify the Department of Health and Human Service's (HHS) Inspector General of any disclosures made by a provider,⁹ as well as any action taken regarding the provider's participation in the program.¹⁰ To ensure that they are not enrolling excluded individuals, States may check any provider seeking Medicaid enrollment against OIG's List of Excluded Individuals/Entities, available on the Internet.

State Standards for Provider Enrollment. Each State sets its own standards for enrollment of Medicaid providers. Pursuant to 42 CFR § 431.51(b)(1), Medicaid services may only be provided by individuals or organizations that are qualified to provide a specified service. States differ in their definition of a "qualified" provider. State standards for Medicaid DME provider enrollment can range from requiring that the DME business location be accessible during reasonable business hours to requiring that Medicaid applicants enroll in the Medicare program as a condition of Medicaid enrollment. In addition, States may verify whether providers meet standards at initial enrollment, and may also review providers after enrollment to determine whether providers continue to adhere to State standards. One method of verifying whether a DME provider meets State standards is to conduct site visits of the provider's location.

After a State approves an applicant to provide DME, the State assigns a Medicaid DME identification number entitling the provider to receive reimbursements under the State's Medicaid program.

Medicare DME Provider Standards

Unlike Medicaid, Medicare provider enrollment requirements are standardized across all States (except licensure requirements that vary from State to State). CMS contracts out the enrollment process to the National Supplier Clearinghouse (NSC). At the time our review was conducted, Medicare DME providers were required to meet 21 standards in order to obtain billing privileges.¹¹ These standards include accessibility during reasonable business hours, liability insurance, and compliance with Federal and State licensure requirements.¹² (See Appendix A for the complete listing of Medicare standards.) Compliance with most of these standards is verified by NSC through site visits. OIG has previously found that the site visit process improved supplier compliance with Medicare standards.¹³ Other types of standards are verified when the application is reviewed.

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For example, the analyst reviewing the provider application will verify liability insurance through the insurance company underwriting the policy.

In addition to initial enrollment, Medicare also requires providers to renew their application every 3 years, which is referred to as reenrollment. Medicare DME providers must certify in their applications that they meet and will continue to meet all Medicare standards. NSC conducts site visits of the providers during reenrollment to verify continued compliance with the standards.

There are planned changes for provider enrollment in the Medicare program. Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Medicare program to develop and implement quality standards for DME suppliers.¹⁴ Pursuant to a final rule published by CMS, all suppliers are required to meet quality standards included as part of the accreditation process to participate in and bill the Medicare program.¹⁵ According to the final rule, CMS will phase in the accreditation process of DME suppliers.¹⁶ Until these changes are fully implemented, NSC will continue with its enrollment responsibilities, which include conducting site visits and reenrolling DME providers.

Vulnerabilities in Medicare Enrollment

Both OIG and GAO have identified vulnerabilities in the Medicare enrollment process. In a 1997 report, OIG recommended numerous improvements to the Medicare enrollment process, including surety bond requirements and site visits of DME suppliers.¹⁷ In a follow-up report in 2001, OIG determined that Medicare's expansion of oversight activities improved compliance with Medicare standards, but that more measures were needed to receive a higher compliance rate.¹⁸ In 2005, GAO determined that CMS should improve DME supplier compliance with Medicare standards.¹⁹ Among its recommendations, GAO stated that CMS should both strengthen its procedures to verify that suppliers were meeting the Medicare standards, as well as enhance the standards themselves.

Dual Enrollment and the National Provider Identifier

Any Medicaid provider who voluntarily enrolls in the Medicare program, or is required to enroll in Medicare by a State agency as a condition of Medicaid enrollment, is required to meet Medicare standards. When the new quality standards and the accreditation process are implemented, such providers will fall under these new

requirements. CMS does not track the number of DME providers exclusively enrolled in the Medicaid program, nor those who are dually enrolled in both Medicare and Medicaid. One of the obstacles in determining these figures is the absence of a unique, national identification number for providers. The Health Insurance Portability and Accountability Act of 1996 required the Secretary of HHS to implement unique identifiers for all health care providers. In January 2004, the National Provider Identifier (NPI) was established by final rule. All Medicare and Medicaid DME providers that are covered health care providers, as defined by the rule, are required to use an NPI by May 2007.²⁰ In the future, the NPI may provide data to determine which providers are dually enrolled in both Medicare and Medicaid.

METHODOLOGY

Scope

The purpose of our evaluation was to provide a report that broadly outlined the standards used by selected States for their DME provider enrollment programs; determine the extent to which States verify that providers meet these standards; and determine the extent to which these States reenroll Medicaid DME providers. We examined reenrollment because the Medicare program uses reenrollment to verify continued compliance with the Medicare standards; we sought to determine if States similarly had reenrollment processes in place. Reenrollment is important as it provides States the opportunity to verify continued compliance with their standards.

Our evaluation was designed to provide descriptive information about State-implemented standards, and we did not assess the effectiveness of the standards. Also, we did not determine whether States were meeting the specific Federal requirements pertaining to disclosure of ownership and criminal history disclosure.²¹

For this evaluation, we defined DME provider enrollment standards as any safeguards, guidelines, requirements, or practices that State provider enrollment programs use to protect the integrity of their Medicaid DME programs. We included 14 States and the District of Columbia in our evaluation of DME provider enrollment standards (referred to as 15 States throughout this report). The 15 States are listed in Appendix C. These 15 States represent a mix of States with different population sizes; are geographically diverse; and include States participating in the Medi-Medi program.²² While results from

this report cannot be projected to other States, our selection process ensured that a diverse selection of States were included to provide insight on DME provider enrollment practices.

Data Collection

To meet our three objectives, we collected data through e-mail and telephone surveys. The surveys included questions addressing the following areas:

- DME provider enrollment standards that must be met for an applicant to be enrolled as a Medicaid provider (e.g., licensure and accessibility during reasonable business hours),
- The extent to which States routinely verify that providers meet State standards,
- The extent to which States routinely conduct site visits as part of their verification processes, and
- Whether States reenroll Medicaid DME providers, what activities occur during reenrollment, and how often reenrollment occurs.

As a part of the e-mail survey, we also requested that States submit provider enrollment application packages as well as written documents that supported their reported standards. We used this information to conduct a document review. This was a selective review of the general accuracy of State-reported information. If there were discrepancies between State documentation and State responses, we worked with the States to resolve these differences.

The data collection was completed during September and October 2005. Therefore, unless otherwise noted, the standards included in this report reflect standards in place during that timeframe. If State responses were incomplete, we continued to follow up with States throughout the fall of 2005.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

States that we reviewed employed a variety of standards for DME provider enrollment

All 15 States reported various DME provider enrollment standards.

Table 1 provides the standards that 15 States reported had been implemented specifically for their Medicaid programs. For the definition of each standard listed below, refer to Appendix B. For a State-by-State comparison of Medicaid standards, refer to Appendix C.

**Table 1: State Enrollment Standards Reported by 15 States
September – October 2005**

Standard	States With Implemented Standards	Percentage Who Have the Standard
Criminal History Disclosure	15/15	100%
Ownership Disclosure	15/15	100%
P.O. Box Prohibition	14/15	93%
Primary Phone Number	12/15	80%
Licensure	8/15	53%
Records Storage	8/15	53%
Signage and Hours Posted	8/15	53%
Accessibility During Reasonable Business Hours	8/15	53%
Medicare Enrollment Required	7/15	47%
Inventory	6/15	40%
Liability Insurance	3/15	20%
Surety Bonds	1/15	7%
Moratorium*	1/15	7%

*A moratorium for provider enrollment is a safeguard that prevents the entry of new providers into the program. This differs from the other standards in Table 1, which are standards that providers must meet.

The standards in Table 1 provide safeguards for DME programs in different ways. For example, standards such as the P.O. Box Prohibition and the requirement to post a sign and hours of operation help to ensure that an appropriate physical facility is being operated. Additionally, in eight States, providers must comply with State licensure requirements. Licensure is often required to make certain that guidelines or regulations are being followed to ensure that providers are offering services in a correct and safe manner to beneficiaries. The type of licensure that is required varies from State to

State; some States only require a sales tax permit, while others require a professional license, such as a DME or a hearing aid license.

Two other standards included in Table 1 illustrate additional ways States protect their DME programs from fraud and abuse. Florida requires providers to obtain a surety bond as a condition of participation in the Medicaid program. Surety bonds help indemnify the State against fraud by requiring enrolling providers to post a bond that can be later used by the State to recover any losses incurred by the provider. Florida’s surety bond amount was \$50,000. Two other States had taken steps to develop a surety bond requirement, but due to opposition from the provider community, these initiatives have not been implemented. In another example of State safeguards, California imposed a moratorium for new DME providers, an initiative that began in 1999. Through the moratorium, California stopped issuing new Medicaid DME provider numbers, with a few exceptions (e.g., a provider who has restructured ownership).

As noted in Table 1, seven States required providers to enroll as Medicare DME providers. Therefore, Medicaid providers in these States were subject to Medicare standards, which include all of the State standards included in Table 1, except surety bonds and moratorium.²³ For the seven States with the requirement to enroll in Medicare, Table 1 includes only those standards that States reported they had instituted specifically for their Medicaid program. If a State did not report having a particular standard that is indirectly addressed through the requirement to enroll in Medicare, we did not classify the State as having the standard in Table 1. However, Appendix D provides analysis of the effect of the Medicare requirement on the total number of standards.

Most States that we reviewed were not routinely verifying whether providers met all State DME provider enrollment standards

States can verify whether providers meet some standards through site visits, while other standards can be verified when

the application is reviewed. For example, a State’s review process of providers’ applications can include verifying the legitimacy of licenses online via State databases or Web sites, and verifying primary phone numbers via Web searches or calling the number directly.

While the States in our review requested information from providers during the enrollment process, we found that gaps exist between standards and State verification processes. For example, while all 15

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States requested that applicants disclose their criminal history, only 2 States routinely conducted criminal background checks at enrollment. Florida and New York were the only States in our review that verified all of their reported standards.

Table 2 outlines State standards, the number of States verifying providers met each standard, and the percentage of States verifying whether providers met the standards. Appendix B provides a definition of each standard and verification process listed below. Appendix C details totals for each State.

Table 2: State-Implemented Standards vs. Verification Process 15 Reviewed States* September - October 2005			
Type of Standard*	Number of States With Standards	Number of States That Verified the Standard	Percentage That Verified the Standard
Criminal History Disclosure	15	2	13%
Ownership Disclosure	15	14**	93%
P.O. Box Prohibition	14	10	71%
Primary Phone Number	12	5	42%
Licensure	8	7	88%
Records Storage	8	5	63%
Signage and Posted Hours	8	8	100%
Accessibility During Reasonable Business Hours	8	7	88%
Medicare Enrollment Required	7	7	100%
Inventory	6	6	100%
Liability Insurance	3	2	67%
Surety Bonds	1	1	100%

*The safeguard of moratorium that was listed in Table 1 was not applicable to this table, because a moratorium stops issuance of DME numbers to new providers.

**We define verification of ownership disclosure as States checking owners against OIG's List of Excluded Individuals/Entities.

Seven of the fifteen States did not routinely conduct site visits at enrollment to verify whether providers were meeting State standards

Site visits can determine whether certain information provided during enrollment is accurate and the provider is operating a legitimate DME business. Site visits are often the only method available to verify specific standards. For example, a site visit enables a State to determine whether a provider’s business is accessible during reasonable business hours. Other standards that can be verified through site visits include: records storage, inventory, and posted sign and hours of operation.

Seven of the fifteen States did not conduct routine site visits as part of their provider enrollment process. However, four of these States did require Medicare enrollment as a condition of Medicaid enrollment. By requiring Medicare enrollment, applicants should receive site visits by NSC in order to enroll in the Medicare program. The remaining three States neither performed routine site visits to verify enrollment information nor required Medicare DME participation as a condition of enrollment. Without State-conducted site visits or enrollment in Medicare, Medicaid-only providers were unlikely to have their DME business reviewed through routine site visits at enrollment.

Eight of the fifteen States routinely conducted site visits at enrollment.²⁴ Four of the eight States conducting site visits reported that site visits were the most effective component of their provider enrollment standards and verification processes.

Four of the fifteen States routinely reenrolled DME providers; two additional States reported recent initiatives to reenroll providers

Connecticut, Florida, Georgia, and Illinois routinely reenroll DME providers, but reenrollment in these

States does not include routine site visits. An example of the types of activities that occur at reenrollment is illustrated by the State of Florida. In that State, the provider must verify basic demographic information, such as name, tax identification number, address, telephone number, and whether or not a change of ownership has occurred. Further, providers are required to sign a new provider agreement at reenrollment. The timeframes the four States used for reenrollment varied as specified below:

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- Every 2 years (Connecticut and Georgia),
- Every 5 years (Illinois), and
- Once every fiscal agent contract, approximately every 5 years (Florida).

Although New Jersey and California did not report conducting reenrollment on a routine basis, both States reported recent initiatives to reenroll providers. New Jersey reported that they were reenrolling all providers for the first time; this process is expected to continue during 2006. California recently completed a 5-year effort to reenroll all DME providers. From 1999 through 2004, 646 of the 1,420 DME providers voluntarily chose to leave the program.²⁵ In addition to reenrollment, the State restricted entry of new DME providers into California Medicaid, imposing a moratorium for new DME providers beginning in 1999.

Nine States did not conduct Medicaid reenrollment. However, five of these nine States did require that the provider be enrolled in the Medicare program. For Medicare reenrollment, providers must certify every 3 years that they meet Medicare standards and should receive site visits as a part of the Medicare reenrollment process. In contrast, the remaining four States neither routinely reenrolled DME providers nor required that providers be enrolled in Medicare. Therefore, providers in these States were unlikely to be routinely reviewed for continued compliance with provider enrollment standards, unless they had voluntarily enrolled in the Medicare program.

► C O N C L U S I O N

Our review determined that the 15 States reviewed employed a variety of provider enrollment standards to protect their Medicaid DME programs. Some of these standards, such as providers posting a sign and hours of operation, help ensure that an appropriate physical facility is being operated. Also, standards include licensure of providers and obtaining surety bonds. In addition, seven of the States that we reviewed also required Medicaid providers to enroll as providers in the Medicare program, which subjects Medicaid providers in these States to Medicare standards.

Despite the presence of these standards, we determined that most of the 15 States were not verifying whether providers met all provider enrollment standards, and that 7 of the 15 States were not conducting routine site visits at initial enrollment. In addition, only 6 of the 15 States reported that they either routinely reenrolled providers, or had recent initiatives to reenroll providers.

► E N D N O T E S

¹ “Medical Equipment Suppliers: Assuring Legitimacy” (OEI-04-96-00240, December 1997).

² “Medicaid: HCFA and States Could Work Together to Better Ensure the Integrity of Providers” (GAO/T-HEHS-00-159, July 18, 2000), and “Medicaid Program Integrity: State and Federal Efforts to Prevent and Detect Improper Payments” (GAO-04-707, July 16, 2004).

³ “Opportunities for Congressional Oversight and Improved Use of Taxpayer Funds: Budgetary Implications of Selected GAO Work” (GAO-04-649, May 7, 2004).

⁴ 42 CFR § 440.70(b)(3) and 42 CFR § 441.15(a)(3).

⁵ CMS details information about State Medicaid programs including optional services offered by States in “Medicaid At-a-Glance 2005.” Available online at <http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/MedicaidAtAGlance2005.pdf>. Accessed February 8, 2006.

⁶ 42 CFR § 455.104.

⁷ 42 CFR § 455.106.

⁸ 42 CFR § 1002.3(a).

⁹ 42 CFR § 455.106(b)(1) and 42 CFR § 1002.3(b)(1).

¹⁰ 42 CFR § 455.106(b)(2) and 42 CFR § 1002.3(b)(3).

¹¹ CMS published a final rule on August 18, 2006, at 71 FR 48354, entitled “Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2007; Certain Provisions Concerning Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Suppliers.” In part, this final rule amends the durable medical equipment certification standards regulation at 42 CFR § 424.57(c) by

adding four additional standards. See Appendix A for the standards in place at the time of evaluation, as well as the text of the new standards.

¹² 42 CFR § 424.57(c).

¹³ “Medical Equipment Suppliers: Compliance with Medicare Standards” (OEI-04-99-00670, August 2001).

¹⁴ Pub. L. 108-173, adding section 1834(a)(20) of the Social Security Act.

¹⁵ See 42 CFR § 424.57(c)(24) (as added by the Medicare program final rule at 71 FR 48354 (August 18, 2006)). CMS has posted quality standards for suppliers of DMEPOS on its Web site at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/CMS_DMEPOS_Quality_Standards_081406.pdf.

¹⁶ See the preamble to the Medicare program final rule at 71 FR at 48392.

¹⁷ “Medical Equipment Suppliers: Assuring Legitimacy” (OEI-04-96-00240, December 1997).

¹⁸ “Medical Equipment Suppliers: Compliance with Medicare Standards” (OEI-04-99-00670, August 2001).

¹⁹ “Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers” (GAO-05-656, September 22, 2005).

²⁰ 45 CFR § 162.404.

²¹ Our study included general survey questions to States, including whether States obtain ownership disclosure from providers, and whether States obtain providers’ and business owners’ criminal history disclosures. However, we did not determine whether States fully met the specific Federal requirements for ownership disclosure (42 CFR § 455.104) and criminal history disclosure (42 CFR § 455.106).

²² Medi-Medi is the Medicare-Medicaid match program in which claims data are analyzed to determine vulnerabilities in both programs. By analyzing data from both programs together, patterns may be detected that may not be evident when billings for either program are viewed in isolation.

²³ The eight remaining States did not require providers to be enrolled in the Medicare DME program. For these States, data regarding how many Medicaid DME providers choose to enroll as Medicare DME providers (and, therefore would be subject to Medicare standards) were not available.

²⁴ The eight States that routinely conducted site visits at enrollment were California, Connecticut, Florida, Georgia, Illinois, Nevada, New Jersey, and New York. Connecticut conducted site visits only for Medicaid DME providers that offered services that were not covered by Medicare (e.g., hearing aids), and subsequently were not enrolled in the Medicare program. If a provider was enrolled in Medicare, Connecticut verified the Medicare supplier number and relied on Medicare's site visit verification.

²⁵ California estimated a savings of approximately \$193 million per year from this reenrollment project. The State based this estimate on the average monthly billing for this provider type, which is \$25,000 per month. OIG did not independently assess this estimate.

Medicare Standards

This appendix contains both the standards in place at the time of our review as well as standards recently added by CMS.

The following are the 21 Medicare standards as outlined in 42 CFR § 424.57(c), at the time of our review. The supplier:

- (1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;
- (2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);
- (3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;
- (4) Fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;
- (5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in § 414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);
- (6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in § 414.229 of this subchapter. The supplier must provide, upon

request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location;

(8) Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section. The supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation;

(9) Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation;

(10) Has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual,

the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

- (12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);
- (13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;
- (14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;
- (15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);
- (16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;
- (17) Must comply with the disclosure provisions in § 420.206 of this subchapter;
- (18) Must not convey or reassign a supplier number;
- (19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);
- (20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:
 - (i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

The additional standards recently added by CMS, see footnote 11, are:

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

▶ A P P E N D I X B

This appendix consists of categories and definitions of State provider enrollment standards we developed to analyze State standards for DME providers.

Categories and Definitions for State Provider Enrollment Standards

Accessibility During Reasonable Business Hours: Provider's location must be accessible during reasonable business hours to beneficiaries and to the State.

Accessibility Verified: State verifies that providers are accessible during reasonable business hours.

Criminal History Disclosure: Criminal history must be disclosed by providers.

Criminal History Verified: State conducts criminal background checks of providers.

Inventory: State requires providers to fill DME orders from their own inventory or have contracts in place to fill the order.

Inventory Verified: State verifies that providers fill DME orders from their own inventory or have contracts in place to fill the order.

Liability Insurance: State requires providers to have liability insurance.

Liability Insurance Verified: State verifies that providers have liability insurance.

Licensure: State requires some or all providers to hold a license (e.g., sales tax permit or professional license).

Licensure Verified: State verifies that providers hold appropriate licensure (e.g., sales tax permit or professional license).

Medicare Enrollment Required: State requires Medicaid DME providers to be enrolled in the Medicare program in order to be enrolled in the State Medicaid DME program. Any provider enrolled in Medicare is required to meet Medicare standards (see Appendix A).

States Requiring Medicare that Verify: For State with the Medicare enrollment requirement, State verifies whether the provider is enrolled in Medicare.

Moratorium: State has stopped issuing DME provider numbers.

A P P E N D I X B

Ownership Disclosure: Provider must disclose who has business ownership and/or control of the DME business.

Ownership Reviewed for Exclusions: State checks owners against OIG's List of Excluded Individuals/Entities.

P.O. Box Prohibition: State prohibits the providers from using a P.O. Box or commercial mailbox as their physical facility.

P.O. Box Verified: State verifies that providers are not using a P.O. Box or commercial mailbox as their physical facility.

Primary Phone Number: Provider must have a primary business telephone number.

Primary Phone Number Verified: State verifies the primary business phone number of DME provider applicants.

Records Storage: Provider's physical facility must contain space for storing records (including delivery, maintenance, and beneficiary communication records).

Records Storage Verified: State verifies that provider's physical facility contains space for storing records.

Signage and Hours Posted: Providers are required to maintain a visible sign and posted hours of operation.

Signage and Hours Posted Verified: State verifies that providers are maintaining a visible sign and posted hours of operation.

Surety Bonds: Providers must post a surety bond prior to enrollment.

Surety Bonds Verified: State verifies that providers meet the surety bond requirement.

➤ **A P P E N D I X C**

Table 1: Medicaid Standards Implemented by the 15 States as of October 2005								
State	Accessibility During Reasonable Business Hours	Accessibility Verified	Criminal History Disclosure	Criminal History Verified	Inventory	Inventory Verified	Liability Insurance	Liability Insurance Verified
CA	X	X	X		X	X	X	X
CT	X	X	X		X	X		
DC	X		X					
FL	X	X	X	X	X	X		
GA			X				X	
IL	X	X	X		X	X		
MN			X					
MT			X					
NV	X	X	X				X	X
NJ	X	X	X		X	X		
NY	X	X	X	X	X	X		
NC			X					
OH			X					
TX			X					
WY			X					
Total	8	7	15	2	6	6	3	2

Source: Analysis of State Medicaid DME standards compiled by OIG.

A P P E N D I X C

Table 1 (cont): Medicaid Standards Implemented by the 15 States as of October 2005									
State	Licensure	Licensure Verified	Medicare Enrollment Required	States Requiring Medicare that Verify	Moratorium	Ownership Disclosure	Ownership Reviewed for Exclusions	Primary Phone Number	Primary Phone Number Verified
CA	X	X			X	X	X	X	X
CT	X*	X	X	X		X	X		
DC	X		X	X		X		X	
FL	X	X				X	X	X	X
GA						X	X	X	
IL	X	X				X	X	X	
MN						X	X	X	
MT						X	X	X	
NV	X	X				X	X	X	X
NJ			X	X		X	X		
NY			X	X		X	X	X	X
NC	X	X	X	X		X	X	X	
OH	X	X				X	X	X	X
TX**			X	X		X	X	X	
WY			X	X		X	X		
Total	8	7	7	7	1	15	14	12	5

*For hearing aid dealers only.

**Although Texas does not have a licensure requirement for the purpose of DME provider enrollment, the Department of State Health Services does license all wholesalers and manufacturers of DME, which may include some DME providers.

Source: Analysis of State Medicaid DME standards compiled by OIG.

A P P E N D I X C

Table 1 (cont): Medicaid Standards Implemented by the 15 States as of October 2005								
State	P.O. Box Prohibition	P.O. Box Verified	Records Storage	Records Storage Verified	Signage and Hours Posted	Signage and Hours Posted Verified	Surety Bonds	Surety Bonds Verified
CA	X	X	X	X	X	X		
CT	X	X			X	X		
DC	X	X	X					
FL	X	X	X	X	X	X	X	X
GA	X	X			X	X		
IL	X	X	X	X	X	X		
MN	X	X						
MT	X							
NV	X	X	X	X	X	X		
NJ	X	X			X	X		
NY	X	X	X	X	X	X		
NC	X		X					
OH	X		X					
TX	X							
WY								
Total	14	10	8	5	8	8	1	1

Source: Analysis of State Medicaid DME standards compiled by OIG.

► A P P E N D I X D

Seven States required providers to enroll as a Medicare DME provider in order to become Medicaid providers. Although the purpose of our inspection was to determine the extent to which States themselves had implemented standards and whether States followed the implementation of these standards with a State review of providers to determine if they were compliant, the requirement to enroll in Medicare does provide additional standards for State Medicaid programs. The following table provides analysis of the effect of the Medicare requirement on the total number of reviewed State-implemented standards. Please note the following about the information provided:

- Column A lists each standard. For the definition of each standard, refer to Appendix B.
- Column B provides the number of States that have implemented each standard exclusively through their own Medicaid programs. This column does not include any States with the requirement to enroll in Medicare.
- Column C provides the number of States that have exclusively established each standard by requiring providers to enroll in the Medicare program as a condition of Medicaid enrollment. States in this column do not review if providers have met these standards, and instead rely upon the Medicare program for both the establishment of the standards and verifying and enforcing compliance with each of the standards. We do not know the extent to which such States are aware of Medicare's verification or enforcement of compliance with each of the standards.
- Column D provides the number of States that have both implemented each standard specifically through their own Medicaid programs, as well as through the requirement for Medicaid providers to enroll in Medicare.
- Columns B-D are mutually exclusively; States can only be included in one column.
- Column E provides the total number of States with each standard, by adding columns B-D.

Table 1: Effect of the Requirement to Enroll in Medicare on State Standards*

September – October 2005

Column A: Standard	Column B: Number of States with State- Implemented Standards Only	Column C: Number of States Establishing Standards Exclusively Through Medicare Requirement	Column D: Number of States with <u>both</u> State-Implemented Standards and the Medicare Requirement	Column E: Total Number of States with the Standard (B+C+D)
Criminal History Disclosure	8	0	7	15
Ownership Disclosure	8	0	7	15
P.O. Box Prohibition	8	1	6	15
Primary Phone Number	8	3	4	15
Licensure	8	NA**	NA**	8
Records Storage	5	4	3	12
Signage and Hours Posted	5	4	3	12
Accessibility During Reasonable Business Hours	4	3	4	11
Inventory	3	4	3	10
Liability Insurance	3	7	0	10
Surety Bonds	1	NA***	NA***	1
Moratorium	1	NA***	NA***	1

*Providers enrolled in the Medicare program are subject to Medicare standards in addition to those listed in the table. Refer to Appendix A for a complete listing of Medicare standards.

**Medicare providers must operate their business in compliance with all applicable Federal and State licensure and regulatory requirements, as required in 42 CFR § 424.57(c)(1). However, there is no Federal licensure for Medicare DME providers.

***Surety Bonds and Moratorium are not Medicare requirements, and therefore have been exclusively implemented by States.

Source: Analysis of State Medicaid DME standards compiled by OIG.



A C K N O W L E D G M E N T S

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