

opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

#### List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 18, 2011.

**Thomas D. Shope,**

*Regional Director, Appalachian Region.*

[FR Doc. 2011-7907 Filed 4-1-11; 8:45 am]

BILLING CODE 4310-05-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 424

[CMS-6036-P2]

RIN 0938-AQ57

#### Medicare Program; Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers Safeguards

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would remove the definition of and modify requirements regarding “direct solicitation,” allow DMEPOS suppliers, including DMEPOS competitive bidding program contract suppliers, to contract with licensed agents to provide DMEPOS supplies unless prohibited by State law; remove the requirement for compliance with local zoning laws; and modify certain State licensing requirement exceptions.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 3, 2011.

**ADDRESSES:** In commenting, please refer to file code CMS-6036-P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation

to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6036-P2, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6036-P2, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Katie Mucklow Lehman, (410) 786-0537.

#### **SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any

personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## I. Background

### A. General Overview

Medicare services are furnished by two types of entities, providers, and suppliers. At § 400.202, the term “provider” is defined as a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility (CORF), a home health agency (HHA), or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. The term “provider” is also defined in sections 1861(u) and 1866(e) of the Social Security Act (the Act).

For purposes of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standards, the term “supplier” is defined in § 424.57(a) as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items to Medicare beneficiaries that meet the DMEPOS supplier standards. A supplier that furnishes DMEPOS is one category of supplier. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists. If a supplier, such as a physician or physical therapist, also furnishes DMEPOS to a patient, then the supplier is also considered to be a DMEPOS supplier. The term “DMEPOS” encompasses the types of items included in the definition of medical

equipment and supplies in section 1834(j)(5) of the Act.

The term DMEPOS is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DMEPOS, items furnished in skilled nursing facilities and hospitals. Also, the term DMEPOS is included in the definition of “medical and other health services” found at section 1861(s)(6) of the Act.

Furthermore, the term is defined in § 414.202 as equipment furnished by a supplier or a HHA that—

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- Is for use in the home.

Examples of DMEPOS supplies include items such as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs. Prosthetic devices are included in the definition of “medical and other health services” under section 1861(s)(8) of the Act. Prosthetic devices are defined in this section of the Act as “devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.” Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

Section 1861(s)(9) of the Act provides for the coverage of “leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacement if required because of a change in the patient’s physical condition.” As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as “orthotics and prosthetics.” Under section 1834(h)(4)(B) of the Act, prosthetic devices do not include parenteral and enteral nutrition nutrients and implantable items payable under section 1833(t) of the Act.

Section 1861(s)(5) of the Act includes “surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations” as one of the “medical and other health services” that is covered by Medicare. Other items that may be furnished by suppliers would include the following (among others):

- Prescription drugs used in immunosuppressive therapy furnished

to an individual who receives an organ transplant for which payment is made under this title, and that are furnished within a certain time period after the date of the transplant procedure as noted at section 1861(s)(2)(j) of the Act.

- Extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes as listed at section 1861(s)(12) of the Act.
- Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies included at section 1861(s)(2)(F) of the Act.
- Oral drugs prescribed for use as an anticancer therapeutic agent as specified in section 1861(s)(2)(Q) of the Act.
- Self-administered erythropoietin as described in section 1861(s)(2)(O) of the Act.

#### B. Statutory Authority

Various sections of the Act and the regulations require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made. The following is an overview of the sections that grant this authority.

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program. Under this authority, this proposed rule will require the collection of information from providers and suppliers for the purpose of enrolling in the Medicare program and granting privileges to bill the program for health care services furnished to Medicare beneficiaries.

- Section 1834(j)(1)(A) of the Act states that no payment may be made for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number. In order to obtain a supplier billing number, a supplier must comply with certain supplier standards as identified by the Secretary.

We are authorized to collect information on the Medicare enrollment application (that is, the CMS-855, (Office of Management and Budget (OMB) approval number 0938-0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by Title XVIII of the Act.

In the August 27, 2010 we published a final rule (75 FR 52629) regarding DMEPOS supplier standards which became effective on September 27, 2010.

## II. Provisions of the Proposed Regulations

This proposed rule would apply to all DMEPOS suppliers and would revise several of the DMEPOS supplier standards set forth at § 424.57(c).

With the passage of the Affordable Care Act and efforts to focus on waste, fraud, and abuse of our Medicare system, one of our goals has been to reduce expenditures and provide better quality and access to care. This rule is in furtherance of this goal but also addresses the realities that certain suppliers confront as they attempt to provide quality care and maintain access for beneficiaries.

To ensure that DMEPOS suppliers understand how CMS interprets the DMEPOS supplier standards, we are revising certain supplier standards specified in § 424.57(c). Further, we are clarifying our interpretation of these provisions so as to ensure that our approach protects against fraud, waste, and abuse but also preserves access to services for our beneficiaries.

#### A. Direct Solicitation

The August 27, 2010 final rule implemented an expansion of a provision regarding the “direct solicitation” of Medicare beneficiaries by DMEPOS suppliers in § 424.57(c)(11). The final rule enlarged the scope of the provision beyond prohibiting unsolicited telephone contacts to include in-person contacts, e-mail, and instant messaging. We continue to be concerned about the potential for abuse caused by “direct solicitation” by DMEPOS suppliers and will continue to evaluate DMEPOS supplier marketing practice to ensure our beneficiaries are protected from abusive practices. Based upon our continuing need to evaluate these practices, we believe further investigation is necessary to determine how the agency plans to address this concern. In the interim, we intend to instruct Medicare contractors to continue applying the restrictions on telephone solicitation that were in effect before publication of the August 27, 2010 final rule, instead of implementing the final rule’s requirements regarding “direct solicitation.”

The original intent of the August 27, 2010 final rule was to limit the circumstances in which DMEPOS suppliers could directly contact beneficiaries. The purpose was to inhibit the direct, coercive, and targeted solicitation of our nation’s senior citizens. We are concerned that these solicitations and subsequent purchases can be fraudulent or abusive in nature,

which may result in monetary increases in health care costs and further drains on the Medicare Trust Fund.

Since publication of the August 27, 2010 final rule, we discovered that implementation of the expanded portions of this provision as written is unfeasible. The definition of “direct solicitation” has been criticized as overly broad as it covers some types of marketing activity outside the bounds of what we intended to prohibit under our regulations. Thus, we are proposing to revise § 424.57(a) to remove the definition of “direct solicitation” and revise our regulations at § 424.57(c)(11).

The supplier standard at § 424.57(c)(11) currently states that suppliers must do the following:

Agree not to make a direct solicitation (as defined in § 424.57(a)) of a Medicare beneficiary unless one or more of the following applies:

(i) The individual has given written permission to the supplier or the ordering physician or nonphysician practitioner to contact them 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.

We propose to revise this supplier standard to remove the prohibition against suppliers’ “direct solicitation” of patients, which included, but was not limited to, a prohibition on telephone, computer e-mail or instant messaging, or in-person contacts and to revert to restrictions on suppliers effective before publication of the August 27, 2010 final rule. Thus, we are proposing to remove the definition of “direct solicitation” and to revise the supplier standard at § 424.57(c)(11) to read as follows:

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.

Although we are proposing to modify the supplier standard on direct solicitation at § 424.57(c)(11), we will continue to actively monitor the issue of potentially unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries. In the event we believe that we need to take action to limit these types of communications, we will engage in further rulemaking to address this concern.

#### *B. Contractual Arrangement Issues*

In the August 27, 2010 final rule, we sought to ensure oversight of DMEPOS suppliers by adding an additional layer of oversight in the form of State law. The absence of express State law in certain areas of DMEPOS suppliers oversight has led to confusion among suppliers as to who they may contract with under our programs. We are seeking to clarify that contracting with an individual or entity for licensed services is permissible in the absence of an express prohibition. In addition, the existing supplier standards permits competitive bidding program contract suppliers to contract for licensed services if such contracting is permitted by the State where the licensed services are performed. As with other suppliers, we believe contract suppliers may contract for licensed services in the absence of an express State prohibition. By making the proposed clarification (that is, it is permissible for suppliers to contract for licensed services in the absence of an express State prohibition), we believe the requirements for contract suppliers are also clarified and that the reference to competitive bidding program contract suppliers in the existing regulation is unnecessary and redundant. Therefore, we are proposing to revise § 424.57(c)(1)(ii) by -(1) removing the reference to contract suppliers; and (2) specifying that a DMEPOS supplier may contract with an individual or other entity to provide the licensed services unless expressly prohibited by State law.

Suppliers are reminded that they must always comply with any applicable Federal and State laws, including, without limitation, those related to fraud and abuse.

#### *C. Local Zoning Requirements*

In the August 27, 2010 final rule, we finalized regulations at § 424.57(c)(1)(iii), that required DMEPOS suppliers to comply with all local zoning requirements. The requirement that suppliers comply with local zoning requirements was originally intended to add an additional

level of protection to the Medicare program by helping to prevent waste, fraud, and abuse. Under this new zoning compliance requirement, we could ensure DMEPOS suppliers were actually providing goods and services to Medicare beneficiaries in a physical location rather than out of a residence, a practice often prohibited by municipal code zoning requirements.

However, because State and municipal laws vary considerably and are often subject to frequent changes, we believe that the task of ensuring suppliers comply with local zoning laws is best left to the States. Our contractors do not have access to the information needed to verify each and every compliance requirement, nor are they aware of municipal code provisions, including zoning exceptions, needed to complete compliance verification.

Therefore, we are proposing to remove the language in § 424.57(c)(1)(iii) which requires DMEPOS suppliers to comply with local zoning requirements as part of the supplier standards. We note that DMEPOS suppliers would still be required to comply with all applicable Federal and State laws to comply with the supplier standards. Furthermore, suppliers are still required to comply with all applicable local zoning requirements. However, we believe that allowing local municipalities to enforce their zoning requirements is most appropriate since the local municipalities are most familiar with their respective requirements and have jurisdiction over these matters.

#### *D. State Licensing Requirement Exceptions*

DMEPOS supplier standards require that DMEPOS suppliers maintain a physical facility on an appropriate site as specified in § 424.57(c)(7)(i). Currently, § 424.57(c)(7)(i)(A) states that DMEPOS suppliers must meet certain square footage requirements. This provision has an exception for State-licensed orthotic and prosthetic professionals providing custom fabricated orthotics or prosthetics in private practice. We are proposing that if a State does not offer licensure for orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, then those non-State licensed suppliers in private practice would also meet the exception. However, if the suppliers’ State does offer licensure for this practice area, the exception would apply only to those holding the applicable State license.

Therefore, we propose to modify § 424.57(c)(7)(i)(A) to add a provision

that allows prosthetic and orthotic professionals to qualify for the minimum square footage exception if the State does not offer licensure. We are proposing this modification because we believe that due to the variations in State licensing procedures, comparable practitioners should not be excluded under this rule. However, if a State does offer licensure for such professionals, the orthotics and prosthetics professionals would be required to obtain licensure in order to qualify for the exception to the minimum square footage requirement set forth in § 424.57(c)(7)(i)(A).

In addition, our current regulations at § 424.57(c)(30)(i) state that suppliers must be open to the public a minimum of 30 hour per week. Paragraph (c)(30)(ii)(B) of this section specifies an exception to the minimum hours of operations requirement for licensed non-physician practitioners whose services are defined in section 1861 (p) and (g) of the Act. We note that section 1861(p) and (g) of the Act define certain outpatient physical therapy services and certain outpatient occupational therapy services, respectively. Therefore, to clarify which non-physician practitioners qualify for the minimum hours of operations exception, we are proposing to revise § 424.57(c)(30)(ii)(B) by removing the phrase “licensed non-physician practitioners” and more specifically referring to the applicable sections of the Act. This also should remove any associated confusion that the public has regarding the impact of licensure in meeting this exception.

### III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

### IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order

12866 on Regulatory Planning and review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 to \$34.5 million in any 1 year. (For details, see the Small Business Administration’s Web site at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13> (refer to the 620000 series). There are four categories of provider revenues listed, \$7.0, \$10.0, \$13.5, and \$34.5 million or less). Individuals and States are not included in the definition of a small entity.

We are not preparing an analysis for the RFA because the Secretary has determined that this rule will not have a significant economic impact on a substantial number of small entities. We have determined that the RFA is reasonable given that the provisions contained in this proposed rule are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs. We also believe that the regulatory impact of this proposed rule is negligible and not calculable. This proposed rule would revise and clarify our current policy in the DMEPOS supplier standards covered in § 424.57. Therefore, we anticipate a minimal economic impact, if any, on small entities.

As of March 2008, there were 113,154 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were only approximately 65,984 unique billing numbers. We believe that approximately 20 percent of the DMEPOS suppliers are located in rural areas.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals. Any language herein impacting rural institutions will only serve to place fewer restrictions on these entities, creating a small burden, if any. We understand that a large number of DMEPOS suppliers fall into this category, however these provisions are very narrow in scope and we expect that legitimate DMEPOS suppliers are already meeting these provisions.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. In 2011, that threshold was approximately \$136 million. This rule does not mandate expenditures by State, local, or tribal governments, in the aggregate, or by the private sector of \$135 million and therefore no analysis is required.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

We have considered alternatives to all of the provisions.

For instance, to reduce the burden associated with the provision limiting “direct solicitation,” but also to establish some standards of conduct and

beneficiary protection, we are relaxing the current rule barring “direct solicitation” and are reverting to the requirements in place prior to the August 27, 2010 final rule. We did consider the alternative of not proceeding with the proposed provisions; however, we believe that the proposed rule is necessary to ensure consistency and clarity with regard to supplier standards. In addition, we are relaxing our standards to enable certain nonphysician practitioners to more easily provide access to care for our beneficiaries by reducing the burden associated with the provisions limiting licensed professionals, zoning requirements, and addressing certain contractual arrangement issues.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 424**

Emergency medical services, Health facilities, Health professionals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposed to amend 42 CFR part 424 as set forth below:

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

1. The authority citation for part 424 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart D—To Whom Payment Is Ordinarily Made**

**§ 424.57 Amended**

- 2. Section 424.57 is amended by—
  - A. Removing the definition of “Direct solicitation” in paragraph (a).
  - B. Revising paragraph (c)(1)(ii).
  - C. Removing paragraph (c)(1)(iii).
  - D. Revising paragraphs (c)(7)(i)(A) and (c)(11).
  - E. In paragraph (c)(30)(ii)(B), removing the phrase “Licensed non-physician practitioners” and adding the phrase “A physical or occupational therapist” in its place.

The additions and revisions read as follows:

**§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.**

- (c) \* \* \*
- (1) \* \* \*
- (ii) *State licensure and regulatory requirements.* If a State requires

licensure to furnish certain items or services, a DMEPOS supplier—

(A) Must be licensed to provide the item or service; and

(B) May contract with an individual or other entity to provide the licensed services unless expressly prohibited by State law.

\* \* \* \* \*

(7) \* \* \*

(i) \* \* \*

(A)(1) Except for orthotic and prosthetic personnel described in paragraph (c)(7)(i)(A)(2) of this section, maintains a practice location that is at least 200 square feet beginning—

(i) September 27, 2010 for a prospective DMEPOS supplier;

(ii) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010 and before September 27, 2013; or

(iii) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

(2) Orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice do not have to meet the practice location requirements in paragraph(c)(7)(i)(A)(1) of this section if the orthotic and prosthetic personnel are—

(i) State-licensed; or

(ii) Practicing in a State that does not offer State licensure for orthotic and prosthetic personnel.

\* \* \* \* \*

(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.

\* \* \* \* \*

**Authority:** (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 9, 2011.

**Donald M. Berwick,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Approved: February 25, 2011.

**Kathleen Sebelius,**  
*Secretary.*

[FR Doc. 2011–7885 Filed 4–1–11; 8:45 am]

**BILLING CODE 4120–01–P**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 1**

[WT Docket No. 11–40; FCC 11–29]

**Improving Communications Services for Native Nations by Promoting Greater Utilization of Spectrum Over Tribal Lands**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document seeks comment on a range of specific proposals and issues with the objective of promoting greater use of spectrum over unserved and underserved Tribal lands.

**DATES:** Comments are due on or before May 19, 2011; reply comments are due on or before June 20, 2011.

**ADDRESSES:** You may submit comments, identified by WT Docket No. 11–40, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Federal Communications Commission’s Web Site:* <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.

• *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission’s Secretary, Office of the Secretary, Federal Communications Commission.

• All hand-delivered or messenger-delivered paper filings for the Commission’s Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300