COALITION OF
Wound
Care
Manufacturers

July 5, 2011

United States Department of Health and Human Services
Centers for Medicare and Medicaid Services
Room 445G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code: CMS-2328-P
Comments on Proposed Rule –
"Medicaid Program; Methods for Assuring Access to Covered Medicaid Services"

Dear Dr. Berwick:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to submit comments to the Centers for Medicare and Medicaid Services ("CMS") on its proposed rule regarding "Methods for Assuring Access to Covered Medicaid Services." 76 Fed. Reg. 26342 (May 6, 2011). The Coalition represents leading manufacturers of surgical dressings, negative pressure wound therapy and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds.

The proposed rule is designed, in particular, to assure that, when state Medicaid programs alter their reimbursement methodologies for providers of services, they comply with the requirements of Section 1902(a)(30)(A) of the Social Security Act, 42 U.S.C. § 1396a(a)(30)(A). Under this provision, commonly known as the "equal access" requirement, state Medicaid plans must:

> "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the same extent that such care and services are available to the general population in the service area."

42 U.S.C. § 1396a (a)(30)(A) (emphasis added).

The Coalition strongly endorses the critical principle stated in the proposed rule. That is, "access" to a product or service does not exist without a sufficient number of providers

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and the presence of proper reimbursement rates. Given this, we feel very strongly there is an immediate need for the establishment and enforcement of a standardized, transparent, deliberative, and public process for states to follow to truly evaluate the impact on access before HHS would provide an approval of any reduction in Medicaid reimbursement rates or other program changes.

The following are our comments and recommendations regarding the proposed rule:

Equal Access to Particular Products or Services

Coding of products and services is a critical component of adequate rate setting and ensuring access. HCPCS coding has been increasingly problematic over the past decade and is currently challenging Medicaid programs in their attempts to establish appropriate reimbursement. While this issue is certainly not limited to any one product category, it is significantly impacting access to many durable medical equipment, orthotic and prosthetic supplies. The Coalition maintains that Medicaid programs have limited abilities to resolve access issues when the root cause results from broadly defined HCPCS codes that contain products that have disparate features, pricing and clinical applications. Today, Medicaid programs employ the following solutions to ensure continued access to the full range of products:

1.) Maintain higher levels of reimbursement to ensure the most complex products are accessible. This strategy may result in overpayment for basic technology and under payment for more complex technology which could cause some codes to be susceptible to abuse.

2.) Convert the identified codes to a different payment methodology that is either MSRP based or cost based. In these cases, the administrative burden to the State and to providers is increased and there is an increased need for oversight to ensure that the least costly alternative is provided.

3.) A very small number of Medicaid programs have implemented the use of 'U' modifiers to essentially create the necessary codes to allow development of fee schedules. This is a time consuming process and one that requires a high level of technical knowledge to develop adequate codes. Few states have the financial or human resources to take on this task.

4.) Some Medicaid programs advise providers to bill problematic products using miscellaneous codes. This is also burdensome since it increases claims processing costs and time and creates unnecessary program risks in that it is difficult for the Medicaid programs to ensure the pricing for the products are correct which can lead to serious audit issues. (i.e., the Medicaids cannot prove what code should be used for an item and that is was reimbursed appropriately which may result in recoupment)

Unfortunately, there are still Medicaid programs that attempt to ignore complaints of access problems or drag out attempts to resolve the issues. This has an impact on the beneficiaries that need these products or services.

Recommendations: The Coalition recommends that when access issues are identified at a HCPCS code level, that an assessment of a particular code be completed and that an ad-hoc committee of Medicaid staff be created to request adequate HCPCS codes to aid in resolving the identified access issues. However, because few State Medicaid staffs possess the technical knowledge to adequately address coding, experienced stakeholder involvement with the committee should be encouraged. This involvement may include individuals representing health care providers, health industry trade associations and coalitions, health care manufacturers and patient advocacy groups who have the knowledge and experience in the coding, use of and the furnishing of health care services related to durable medical equipment, drugs, biologics, prosthetics and orthotic supplies.

Monitoring and Resolving Identified Access Issues

The proposed rule includes (1.) beneficiary hotline, (2.) surveys, and (3.) ombudsman programs as means for monitoring access. The Coalition believes these are all good tools, but we believe it is imperative for clinicians and other providers to have mechanism available to them to report access issues. This is particularly important when beneficiaries may not be able to articulate their concerns or when they may not be able to identify the particular issue. This is especially true for beneficiaries with significant physical and mental disabilities. To ensure that these individuals have adequate opportunities to be heard and recognized, others must be able to represent their concerns to the Medicaid programs. Caregivers, family members and providers must have processes in place that allow them to represent the voice of Medicaid beneficiaries where appropriate.

Recommendations:

1. The Coalition strongly recommends that Medicaid programs be instructed to immediately resolve identified access problems. Then, a comprehensive assessment of the issue can occur and a full report with plans to resolve the issues can be developed and submitted to CMS. Implementation of the resolution plan can understandably take some time and the Coalition agrees that a one-year cap is appropriate as along as access continues while long term changes are being implemented.

2. As part of the monitoring of identified access issues, the Coalition recommends annual reviews for the related products or services and public town hall formatted meetings to allow stakeholder feedback regarding current access and to update stakeholders on progress regarding implementation of long-term resolutions.

Medicaid Provider Participation and Public Process to Inform Access to Care

1.) The Coalition submits that it is critical to obtain substantive input from beneficiaries, clinicians and providers when changes are contemplated. We recommend the establishment of an advisory group comprised of beneficiaries, beneficiary advocacy groups, clinicians, manufacturer and provider trade associations/coalitions similarly as discussed in the issue above regarding coding. Most states have well-established organizations that are excellent resources of historical information and stand ready to work with the state in a collaborative process.

2.) The Coalition believes that this public process must be conducted in a manner that requires (a.) the public to be informed of the changes in a timely and detailed manner, (b.) allows the public to offer questions and concerns, and (c.) requires the State to formally respond to the questions and concerns presented. It should not just be a process to inform the public of a change. Its purpose should truly be to solicit and respond to input. This process and the related written report prepared by the State should be published for public review PRIOR to the State submitting any proposed changes to HHS.

3.) We strongly support the position that HHS would disapprove a proposed rate reduction or restructuring State Plan Amendment (SPA) if a State does not fully meet the data review and public input requirements.

Public Notice of Changes in Statewide Methods and Standards for Setting Payment Rates

In this section, the Coalition submits the following comments:

1.) A State should be required to provide public notice for ANY proposed change in payment methods and standards. It is too difficult to establish minimum thresholds and to attempt to do so would run the risk of allowing a State to make changes behind closed doors without any public notification.

2.) A "change" should include both a change in payment rate and/or a change in coverage policy.

3.) Public notice should be required to be given by the State at least 90 days before the submission of any proposed SPA or other Medicaid program change.

4.) Once a change is approved, public notice of the change should be given by the State to beneficiaries and providers at least 90 days before the effective date of the change.

5.) While electronic publications play a useful and cost-effective role in notifying the public, there must also be a requirement for the State to identify and initiate contact with stakeholders from the beneficiary, clinician, provider and manufacturer communities. Web postings alone without prompting to these stakeholders would not be sufficient.

6.) Similar to what CMS employs in other areas, a formal Listserv should be established for Medicaid changes. This should allow interested parties to register by State and receive automatic notices from CMS when a State has submitted an SPA or other proposed Medicaid change and whenever CMS makes a decision as to approval or disapproval of Medicaid changes.

Summary

The Coalition agrees that gaining better control of health care costs is an important national initiative. However, this initiative must be a truly collaborative and informed effort involving all stakeholders (federal agencies, state agencies, providers, and beneficiaries) developed and based on the best available data in order to ensure success. One of the key collaborative processes, evaluating access, currently lacks the needed federal guidance and thereby falls short of consistent application by the states. Allowing the reduction of payment rates without carefully examining access could cause great problems for both the payers and the beneficiaries. The changes in the proposed rule, incorporating our comments and suggestions above, will institute major improvements within the Medicaid program and help to safeguard appropriate access for Medicaid beneficiaries.

The Coalition would be happy to serve as a resource to you for assistance or to provide any additional information.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director