June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

The National Home Infusion Association (“NHIA”) is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies as issued in the Federal Register on May 1, 2006.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Currently, NHIA has approximately 1,800 members.

CMS has the unenviable task of developing and implementing within a limited time frame a nationwide competitive bidding program for a large portion of the Medicare program. The proposed rule reflects the hard work that CMS has devoted to this effort. We commend CMS for its efforts to translate the statute into a viable program.

That said, the proposed rule is unlike most proposed rules in that this rule lays out a number of unanswered questions. On a number of important issues, CMS has not committed to a concrete proposal. The preamble section regarding criteria for product selection, wherein CMS
seeks comment on very general criteria for subsequent product selection, and the preamble
discussion regarding the application of competitively bid rates in other areas of the country, are
two examples of this practice. In addition, the Part B quality standards have not been issued yet,
and thus our comments on the proposed rule cannot reflect the impact of the quality standards on
the proposed competitive bidding program.

At this juncture, it is difficult to project what the final rule will look like on a number of
important issues where CMS did not propose a specific course of action. For that reason, we
suggest that CMS issue the final rule as an interim final rule with comment period, so that the
public will see, for the first time, CMS’ directions on an array of issues and thus will have an
opportunity to comment on concrete proposals.

Quality Standards

At the outset, we want to address briefly an issue pertaining to the development of Part B
quality standards for durable medical equipment, prosthetic and orthotic services and items
(DMEPOS). Section 1847(a) of the Social Security Act (hereafter “Act”) requires CMS to
develop quality standards that would apply to the provision of most non-physician Part B items
and services. We applaud this initiative, as these quality standards are important to the
functioning of the competitive bidding program that is the subject of the proposed rule.
Importantly, however, the quality standards are not limited to those items subject to competitive
bidding. The standards will apply equally to those non-physician Part B items and services that
are not subject to competitive bidding and which will continue to be reimbursed pursuant to the
otherwise applicable payment methodologies.

There should be no argument with the principle that Medicare payments, whether
determined by fee schedule or via competitive bidding, should be sufficient for efficient
suppliers to comply with the quality standards. The standards will have little meaning or effect if
Medicare payment levels are woefully inadequate in relation to the costs associated with
complying with the quality standards. This is, we believe, an important point that CMS should
affirm in the final rule.

With the development of meaningful quality standards, we believe CMS and the OIG
now are required to factor the costs of compliance with these standards into their assessments of
adequacy of reimbursement. It would be a most illogical development if these assessments
continue to be conducted as if the quality standards have no applicability, meaning or cost. We
request that CMS acknowledge that the costs of compliance with applicable quality standards
should be taken into account in future consideration of reimbursement issues, both within and
outside the competitive bidding program.
Executive Summary

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. Home infusion therapy is one of the most service-intensive and invasive therapies covered under Part B of the Medicare program. Medicare Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

3. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number is misleading and incorrect. It includes expenditures made for insulin and insulin pumps for patients with diabetes, which are provided by entities other than infusion pharmacies and is largely a different market than infusion. It includes drugs that have sole or limited national distribution arrangements with particular pharmacies, so that there would continue to be a very limited number of infusion pharmacies that supply the drugs to Medicare beneficiaries. In addition, it includes drugs that are administered to the “sickest of the sick” patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million, which represents less than 0.8% of DMEPOS expenditures for that year.

4. Enteral nutrition is not a good candidate for inclusion in the first phase of the competitive bidding program. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services within the scope of the competitive bidding program. It creates serious policy and operational issues for nursing homes as well as for CMS itself. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

5. If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients.

6. If CMS ultimately subjects enteral nutrition to competitive bidding, it should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure
that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

7. The competitive bidding areas should be limited to the geographic scope of the selected metropolitan statistical areas (“MSAs”), and should not encompass contiguous areas.

8. The proposed gap-filling provisions are too vague and undefined, and appear to be in conflict with the limitations on CMS’ authority to modify existing payment rates. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders as to how existing payment levels can and should be adjusted when existing codes are modified.
Criteria for Item Selection

We understand that competitive bidding is intended to be a far-reaching initiative that will achieve two important objectives: (1) improve the level of care for Medicare beneficiaries requiring Part B items and services, and (2) reduce Medicare expenditures, including the amount of beneficiary co-payments.

Both, obviously, are admirable goals. For the reasons described herein, however, we believe that infusion drugs, supplies and pumps covered under the DME benefit and enteral formulas, supplies and equipment covered under the prosthetic device benefit are poor candidates for inclusion in the competitive acquisition program, particularly in the initial phase of the program.

DME-Covered Infusion Pumps and Related Drugs

Home infusion therapy involves the administration of medication through a needle or catheter. Typically, infusion therapy means that a drug is administered intravenously, but the term also may refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes. Diagnoses requiring infusion therapy include infections that are unresponsive to oral antibiotics; cancer and cancer-related pain; and congestive heart failure. Common prescription drug therapies administered via home infusion include antibiotics, chemotherapy, and pain management. Home infusion therapy is indicated for patients with medical conditions that cannot be treated effectively with oral medications.

Policy Bases for Excluding Infusion Pumps and Related Drugs from Competitive Acquisition Program

Home infusion therapy is one of the most clinically complex areas within the scope of the competitive bidding program. Infusion therapy involves more than the delivery of infusion drugs to patients. Patients receiving home infusion therapy require an array of professional services, including the following:

- Initial patient evaluation and assessment
- Development and implementation of the patient care plan
- Compounding and dispensing of infusion medications and equipment
- Ongoing clinical monitoring and treatment plan oversight
- Care coordination
- Provision of on-call services and patient discharge services.

These services are provided by specialized home infusion pharmacies that must satisfy licensing and other regulatory requirements imposed by state pharmacy boards as well as accreditation standards required by most third-party payers. For a complete description of the necessary functions and costs associated with the safe and effective administration of home infusion drug therapy, see Appendix A.
Current Part B coverage of home infusion therapy is limited to what is covered under the DME benefit, wherein coverage is based on the use of an item of DME – in this case, an infusion pump – and extends only to a few designated drugs. Medicare Part B is unique in this approach to home infusion therapy coverage, as most other payers define and cover home infusion therapy as a professional service under a major medical benefit. While Part B coverage for infusion therapy is keyed to the involvement of an infusion pump, it should be noted that the infusion pump itself is just one component of care in the provision of home infusion therapy.

Instead, this is an area of therapy that is clinically possible in the home primarily because of the specialized professional services provided by home infusion pharmacies. These services require close contact between the infusion pharmacy and patient, and the effective and safe provision of home infusion therapy is dependent in large part of the development and maintenance of a trusting relationship between the infusion pharmacy and the patient (and the patient’s family and caregivers).

No one has seriously suggested that competitive bidding should be applied to physician services, because the choice of a personal physician is a very personal one. While there are differences in degree, for infusion therapy the patient’s choice of an infusion pharmacy also is very personal.

We suggest that as a starting point for the selection of items to be subject to the first phase of the competitive bidding program, CMS should focus first on those products that are not service-intensive. Certainly, home infusion therapy, which is perhaps the most service-intensive area under consideration, is a poor candidate for this phase of the program.

There are other important policy reasons why infusion drugs and pumps are not suitable at this time for competitive bidding. Home infusion therapy is unique in the DMEPOS category in that while 23 drugs can be covered in the home under limited circumstances under Part B, since January 1, 2006 hundreds of home infusion drugs are now coverable under Part D. Therefore, the implementation of competitive bidding for home infusion under Medicare Part B should not be considered without contemplating the effect this would have on the already extremely complicated Part B-Part D drug coverage issues.

It is easy to foresee that a patient may have a need for both a Part B-covered drug as well as a Part D-covered drug i.e., a Part B cancer drug and a Part D IV antibiotic drug. This would be a very likely occurrence because many infusion patients are receiving more than one therapy, and most infusion drugs are coverable under Part D. The patient, mostly likely a dual eligible beneficiary in the case of home infusion, may have to go to more than one pharmacy to obtain the needed drugs because the pharmacy that supplies the Part D drug may not be a contract supplier under the competitive bidding program for the Part B drug. At the very least, Medicare beneficiaries should be spared that ordeal. In addition, there would be important coordination of care concerns at issue here. The involvement of more than one pharmacy in the treatment of the patient increases the possibilities of mistakes and the prescription of several contra-indicated medications, which could have serious consequences for the patient and result in increased costs
of care. It also would create further confusion for discharge planners, who already are beset with a bewildering array of Part B – Part D coverage issues.

We believe that CMS should exclude from the first phase of the competitive acquisition program infusion pumps and related drugs, as well as any product category where, as here, coverage is divided up among multiple parts of the Medicare program. The Medicare program should avoid the illogical situation where it is encouraging infusion pharmacies to participate in Part D for the provision of home infusion therapy while limiting their participation in Part B for the provision of home infusion therapy. CMS should proceed very carefully with pharmacies that also are trying to participate in the Part D outpatient drug program. The Part B and Part D drug coverage issues must be resolved, or at least far better coordinated than they are now, before CMS subjects the Part B portion of the home infusion area to competitive bidding.

In addition, the application of CMS’ factors for determining product selection for the 2007 phase makes it clear that Part B-covered infusion drugs and pumps are a poor candidate for inclusion in the competitive bidding program at this time, as described below:

I. **Level of Medicare Expenditures**

CMS proposes to use allowed charges at the product level and at the product category level for the purpose of selecting which items to phase in first under the competitive bidding program.

Infusion drugs, supplies and pumps comprise a very small part of the Part B expenditures. Most infusion drugs that are covered by commercial health plans are not covered under Part B. As indicated above, only 23 infusion drugs are covered under the Part B DME benefit, mostly anti-cancer drugs, inotropic, pulmonary hypertension and pain management drugs.¹

Complicating this analysis is the fact that the Part B infusion pump and related drugs product category is far from homogenous. It should be noted that there are no single products used in home infusion drug therapy that fall within the list of high volume items found in Table 3 in the preamble to the proposed rule. In addition, we believe that the following products within the category should be excluded when attempting to quantify infusion-pump and related drug expenditures (2003 Part B allowed charges are shown in parentheses):

¹ At a PAOC meeting in 2005, CMS circulated a document that indicated that Medicare expenditures for infusion pumps and related drugs amounted to $69,580,260 in 2002. By contrast, the proposed rule lists infusion drugs and pumps as the eighth largest area of expenditure in Part B in 2003, with over $149 million in allowed charges in 2003.

NHIA has been unable to determine precisely how these totals were derived. We believe the disparity in the amounts attributable to infusion pumps and related drugs underscores the confusion and ill-fitting coverage criteria that surrounds Medicare’s policies pertaining to home infusion therapy. It is critical for CMS to understand fully what is involved in the home infusion product category before considering subjecting this area to the competitive bidding program.
a. **Insulin pumps and supplies** ($10,275,629)

b. **IVIG** (only $29,515 in 2003, but increasing thereafter)

c. **Limited distribution products** ($30,747,401 in 2003, but along with IVIG, the fastest growing product areas in this category)

d. **Inotropic Therapies** used to treat patients with Classes III and IV congestive heart failure – milrinone and dobutamine ($26,156,345)

Once these subcategories are excluded, the remaining allowed charges for home infusion therapy products totals $87.4 million, 14th on the list of product categories ranked by level of allowed charges. It must be noted however that this revised total still includes infusion pumps and supplies used to administer limited distribution products and inotropic therapies, since it is impossible to separately identify these expenditures.

For a more in-depth quantitative analysis of infusion pump-related expenditures in recent years highlighting these components of the infusion pump product category, we have prepared a chart that separates out these key subcategories of DME infusion pumps and related drugs. Additional information about the bases for excluding particular drugs and pumps from the infusion product category for the purposes of this analysis are provided on the following page.²

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² To understand the allowed charges for home infusion drug therapy reported in Table 4 in the preamble to the proposed rule, we obtained the Physician Supplier Procedure Summary Master File (PSPSMF) from CMS for 2003. We analyzed the DMERC medical policies for external infusion pumps and the relevant DMERC advisories from 2002, 2003 and 2004 to compile a comprehensive list of all alpha-numeric HCPCS codes for home infusion drug therapy (including external infusion pumps, infusion drugs and supplies) that could have been in effect at any time during calendar year 2003.

Many of these HCPCS codes can be used on claims submitted both by physician offices and home infusion pharmacies. To identify the aggregate allowed charges attributable to DME infusion pumps and related drugs, we calculated the total allowed charges for each code for claims processed by the four DMERCs in the 2003 data file. We aggregated these amounts, and the total allowed charges in 2003 based on our calculations was nearly identical to the total that CMS reported in the proposed rule for this broad category.

The PSPSMF for each calendar year includes procedure-specific billing data for all physician and supplier services provided to Medicare beneficiaries during the calendar year. To be included in the PSPSMF, a claim must be processed by the Medicare Part B carriers on or before June 30th of the subsequent year.

Using CMS’ PSPSMF data from CY2003, we calculated that the total expenditures for home infusion drugs totaled $151,090,407. This total is within 1.3 percent of the number reported by CMS in the proposed rule for DME infusion pumps and related drugs ($149,208,088, see page 25671). As explained in this section, that number encompasses more than the home infusion therapy market, and thus it is larger than what can be attributed to traditional home infusion therapy provided by home infusion pharmacies.
### Allowed Charges For DME Infusion Pumps and Related Drugs, 2002-2004

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>Dollar increase, 2002-03</th>
<th>Rate of increase, 2002-03</th>
<th>2004</th>
<th>Dollar increase, 2003-04</th>
<th>Rate of increase, 2003-04</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total all infusion pump-related expenditures</strong></td>
<td>$141,423,406</td>
<td>$155,017,887</td>
<td>$13,594,481</td>
<td>10%</td>
<td>$198,892,724</td>
<td>$43,874,837</td>
<td>28%</td>
</tr>
<tr>
<td><strong>Insulin Therapies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J1817 – insulin for insulin pump use</td>
<td>-</td>
<td>$1,201,390</td>
<td>$1,201,390</td>
<td>N/A</td>
<td>$3,732,449</td>
<td>$2,531,059</td>
<td>211%</td>
</tr>
<tr>
<td>E0784 – External ambulatory infusion pump insulin</td>
<td>$8,345,127</td>
<td>$9,524,239</td>
<td>$1,179,112</td>
<td>14%</td>
<td>$11,877,197</td>
<td>$2,352,958</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Total insulin related expenditures</strong></td>
<td>$8,345,127</td>
<td>$10,725,629</td>
<td>$2,380,502</td>
<td>29%</td>
<td>$15,609,646</td>
<td>$4,884,017</td>
<td>46%</td>
</tr>
<tr>
<td>% of total infusion pump-related expenditures</td>
<td>6%</td>
<td>7%</td>
<td>8%</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>IVIG Therapies</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J1563 – IG, intravenous, inj, 1 g</td>
<td>-</td>
<td>$29,515</td>
<td>$29,515</td>
<td>N/A</td>
<td>$100,000</td>
<td>$80,485</td>
<td>273%</td>
</tr>
<tr>
<td>Total IVIG-related expenditures</td>
<td>-</td>
<td>N/A</td>
<td>$5,378,677</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of total infusion pump-related expenditures</td>
<td>0%</td>
<td>3%</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td><strong>Pulmonary Hypertension (PH) Therapies</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>J1325 – Epoprostenol, inj, 0.5 mg</td>
<td>$23,479,946</td>
<td>$25,751,157</td>
<td>$2,271,211</td>
<td>10%</td>
<td>$28,647,547</td>
<td>$2,896,390</td>
<td>11%</td>
</tr>
<tr>
<td>Q4077 – Treprostinil, inj, 1 mg</td>
<td>no data in file</td>
<td>$2,816,580</td>
<td>N/A</td>
<td>N/A</td>
<td>$27,358,283</td>
<td>$4,541,703</td>
<td>871%</td>
</tr>
<tr>
<td>K0455 – Infusion pump for uninterrupted epoprostenol admin.</td>
<td>$1,796,803</td>
<td>$2,179,664</td>
<td>$382,861</td>
<td>21%</td>
<td>$2,481,902</td>
<td>$302,238</td>
<td>14%</td>
</tr>
<tr>
<td><strong>Total, PH-related expenditures</strong></td>
<td>$25,276,749</td>
<td>$30,747,401</td>
<td>$5,470,652</td>
<td>22%</td>
<td>$58,487,732</td>
<td>$27,740,331</td>
<td>90%</td>
</tr>
<tr>
<td>% of total infusion pump-related expenditures</td>
<td>18%</td>
<td>20%</td>
<td>29%</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Inotropic Therapies</strong></td>
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</tr>
<tr>
<td>J2260 – Milrinone lactate, inj, 5ml</td>
<td>$27,683,998</td>
<td>$25,743,270</td>
<td>$(1,940,728)</td>
<td>-7%</td>
<td>$29,397,882</td>
<td>$3,654,612</td>
<td>14%</td>
</tr>
<tr>
<td>J1250–Dobutamine HCL, inj, 50mg</td>
<td>$387,412</td>
<td>$413,075</td>
<td>$25,663</td>
<td>7%</td>
<td>$340,222</td>
<td>$(72,853)</td>
<td>-18%</td>
</tr>
<tr>
<td><strong>Total, inotropic therapies</strong></td>
<td>$28,071,410</td>
<td>$26,156,345</td>
<td>$(1,915,065)</td>
<td>-7%</td>
<td>$29,738,104</td>
<td>$3,581,759</td>
<td>14%</td>
</tr>
<tr>
<td>% of total infusion pump-related expenditures</td>
<td>20%</td>
<td>17%</td>
<td>15%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total, Insulin, IVIG, PH, and Inotropic therapies</strong></td>
<td>$61,693,286</td>
<td>$67,658,890</td>
<td>$6,965,604</td>
<td>10%</td>
<td>$103,945,482</td>
<td>$36,286,592</td>
<td>54%</td>
</tr>
<tr>
<td>% of total infusion pump-related expenditures</td>
<td>44%</td>
<td>44%</td>
<td>44%</td>
<td>52%</td>
<td>83%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total infusion pump-related expenditures excluding these drugs</strong></td>
<td>$79,730,120</td>
<td>$87,358,997</td>
<td>$7,628,877</td>
<td>10%</td>
<td>$94,947,242</td>
<td>$7,588,245</td>
<td>9%</td>
</tr>
</tbody>
</table>
Below is a more detailed explanation of why certain categories of products should be excluded from the infusion therapy product category.

1. **Insulin and Insulin Infusion Pumps for Patients with Diabetes**

   Although insulin and insulin infusion pumps are covered under Medicare Part B under the same benefit as home infusion drug therapy, CMS should consider these products separate from the product category for traditional home infusion drug therapies.

   In practice, the provision on infusion pumps for insulin is much less service-intensive than the provision of drug therapies used to treat cancer, intractable pain, congestive heart failure and other common indications for traditional home infusion therapy.

   More importantly, the pharmacies that provide traditional home infusion therapy usually differ from the entities that typically provide infusion insulin pumps and supplies. Insulin and insulin infusion pumps typically are provided by the same suppliers that specialize in test strips, lancets and glucose monitors for patients with diabetes. As a result, when considering home infusion drug therapy as a product category, it is misleading and seriously inaccurate to include insulin and insulin pumps in that product category.

   The PSPSMF data from 2003 reveals that Part B claims for insulin (J1817) and insulin pumps (E0784) accounted for $10,725,629 in allowed charges in 2003. This represents approximately seven percent of all Medicare Part B home infusion drug therapy expenditures in 2003.

2. **Intravenous Immune Globulin (“IVIG“)**

   In calculating the DME infusion pump and related drugs product category, CMS should exclude any amounts attributable to the provision of home IVIG. Home IVIG is not covered under the DME benefit and is not otherwise subject to the competitive bidding provisions of Section 1847(a) of the Act. Rather, home IVIG is covered under Medicare Part B under Section 1861(s)(2)(Z) of the Act, as of January 1, 2004.

3. **Infusion Drugs Used to Treat Patients with Pulmonary Hypertension – Epoprostenol (Flolan®, Glaxo Smith Kline) and Treprostinil (Remodulin®, United Therapeutics Corporation).**

   Pulmonary hypertension is a rare and potentially life-threatening disorder of the lungs in which the pressure in the pulmonary artery (the blood vessel that leads from the heart to the lungs) rises above normal levels. Under the terms of the DMERC medical policies, to qualify for infusion therapy to treat pulmonary hypertension, the patients must have very severe symptoms such as severe shortness of breath with exertion, fatigabilty, angina or syncope.
For a number of unique clinical and practical reasons, competitive bidding would be unworkable for the two infusion drugs that are used to treat pulmonary hypertension in the home setting – epoprostenol (Flolan) and treprostinil (Remodulin).

It is important to note that there is no opportunity to achieve savings under competitive bidding for Flolan because the manufacturer (GlaxoSmithKline) recently entered into a five-year exclusive agreement with Accredo Health, Inc. to provide the drug in the U.S. marketplace. As a result, Accredo Health, Inc. is the only home infusion pharmacy that can provide Flolan to Medicare beneficiaries or other patients in the United States for the foreseeable future. This, then, is not a competitive market and will not be until at least 2010.

Similar threshold problems exist for the potential application of competitive bidding to Remodulin, an alternative treatment for pulmonary hypertension. Manufactured by United Therapeutics, Remodulin is subject to a limited distribution agreement wherein only Accredo Health, Inc., Curascript, Inc. and Caremark, Inc. distribute the drug in the United States. This arrangement will preclude a competitive market for the drug. Thus, Medicare expenditures for Remodulin overly inflate the level of expenditures attributable to infusion pumps and related drugs, since competitive bidding would not be possible for this drug.

With an overall incidence of pulmonary hypertension of only eight per 100,000 population, only a few Medicare beneficiaries in the United States receive Remodulin or Flolan therapy. It would be problematic to fashion a competitive bidding program for such a small number of patients.

The PSPSMF data from 2003 reveals that home infusion claims for epoprostenol (Flolan, J1325), treprostinil (Remodulin, Q4077) and infusion pumps for epoprostenol (K0455) accounted for $30,747,401 in allowed charges in 2003. This represents approximately 20 percent of all Medicare Part B home infusion drug therapy expenditures in 2003. This does not consider other charges incurred in administering these therapies, including the allowed charges for infusion supplies for these two drugs and the allowed charges for the pumps used to administer Remodulin therapy.

4. Infusion Drugs Used to Treat Patients with Classes III and IV Congestive Heart Failure – Milrinone and Dobutamine

Congestive heart failure is a debilitating and life-threatening disorder in which the heart muscle is unable to pump with sufficient force. The heart is unable to keep up with the flow of blood returning to the heart, resulting in fluids collecting in the body.

By the time that the infusion of inotropic drugs in the home setting is indicated (so-called Stage III and Stage IV congestive heart failure), the patient is severely debilitated. For example, under the terms of the DMERC medical policies and well-established standards of care, the infusion of these drugs is not indicated unless the patient becomes short of breath (called dyspnea) by merely performing activities of daily living.
Under the terms of the DMERC medical policy, these drugs are only covered for continuous infusion if the patient has been demonstrated to deteriorate in clinical status when the drug is tapered or discontinued when monitored in the hospital setting. Similarly, these drugs are only covered under DMERC policy for intermittent infusion if the patient has experienced repeated hospitalizations for congestive heart failure. In fact, the Medicare program has identified these patients as an extremely costly group of patients, and that significant cost savings are likely from ensuring access and adherence to their medication therapies.

The application of competitive bidding to the vulnerable population of patients receiving infusion drug therapies for advanced congestive heart failure is unwise. These patients are reliant on these drugs to remain outside of the hospital setting. In fact, the clinical literature includes numerous studies documenting the cost-effectiveness of this class of intravenous drugs to reduce emergency room visits and hospitalizations.

Especially in the early days of competitive bidding, the program could inadvertently (but easily) interfere with access to these drugs or to the level of clinical care associated with providing these therapies. Home infusion therapy is clearly more cost-effective than treatment for exacerbations (or worse) in the acute care setting, but driving the payment rates to significantly lower levels through competitive bidding could jeopardize patient safety and result in increased hospital expenditures.

The PSPSMF data from 2003 reveals that home infusion claims for milrinone (J2260) and dobutamine (J1250) accounted for $26,156,345 in allowed charges in 2003. This represents approximately 17 percent of all Medicare Part B home infusion drug therapy expenditures in 2003 without even accounting for other related charges included in the aggregate figure for home infusion therapy, including the allowed charges for infusion supplies and pumps.

Summary of Issues Regarding Medicare Expenditures for Home Infusion Therapy

Thus, to summarize, the administration of insulin to treat diabetes does not fit well within the product category of traditional infusion pumps and related drugs. Typically, the suppliers that provide insulin for infusion and related products are not the same pharmacies that specialize in traditional home infusion therapies. There also are drugs that are subject to limited distribution arrangements and thus do not present a potentially competitive market for Medicare. In addition, there are a handful of highly complex drug therapies that would be especially problematic, including infusion drugs used to treat pulmonary hypertension and congestive heart failure.

This leaves a potential grouping of less than $88 million for infusion pumps and drugs in the traditional home infusion product category based on 2003 data, a far cry from the $149 million listed in the preamble to the proposed rule.
II. Rate of Growth

The sizeable portion of the increases in allowed charges and payment amounts for infusion pumps and related drugs from 2002-2003, and the vast majority of the increases from 2003-2004, were attributable to the particular drugs described above that should not be considered as part of the infusion therapy product category: Flolan, Remodulin, milrinone, dobutamine, and insulin and insulin pumps. Together, these drugs accounted for $6 million (44 percent) of the $13.6 million increase in allowed charges for infusion pumps and drugs from 2002-2003, and for $36.3 million (83 percent) of the of $43.9 million increase in allowed charges from 2003-2004.\(^3\) In fact, it appears that rate of increase in infusion pumps and related drugs other than these particular drugs decreased from 2003 to 2004. It also should be remembered that Flolan and Remodulin are subject to exclusive or limited distribution arrangements and would not contribute to savings via a competitive bidding process.

III. Demonstration Project Experience

Infusion drugs were not subject to either demonstration project conducted by CMS, and thus there is no evidence that competitive acquisition would be applied successfully to infusion therapy.

IV. Studies and Reports

Infusion therapy is an area that has attracted considerable attention recently because it has defied easy placement in the Medicare coverage scheme. As CMS is well aware, home infusion therapy is covered in the private sector as a medical benefit – not under a medical equipment benefit or as a drug benefit. Medicare coverage of home infusion therapy under the DME benefit is limited to the infusion pump, supplies, and the few infusion drugs covered under Part B. There is no explicit coverage for the professional services and other overhead associated with the safe and effective provision of home infusion therapy.

As a result of Congressional studies and other governmental reports, Congress made significant changes in 2003 in how Medicare Part B pays for outpatient prescription drugs. The MMA changed the general payment methodology from 95 percent of the average wholesale price to 106 percent of the average sales price for a drug. Importantly, however, the incomplete coverage definition under the DME benefit prompted Congress to exempt home infusion drugs from the average sales price payment methodology. Instead, infusion drugs continue to be reimbursed on the basis of average wholesale prices as of October 1, 2003. It was widely understood that the application of the average sales price methodology would have denied infusion pharmacies sufficient reimbursement to provide infusion therapy to Medicare beneficiaries. Payment for infusion drugs continue to subsidize the costs of the professional services and related overhead.

\(^3\) As described above and shown in the above chart, this figure excludes allowed charges related to insulin, insulin pumps and IVIG.
In addition, coverage of home infusion therapy has been a challenge for policymakers and infusion pharmacies alike. As indicated above, most infusion drugs are not covered under Part B; rather, they are coverable under Part D. However, CMS interprets Part D as covering only infusion drugs and retail drug-like dispensing functions. Consequently, most of the services are not covered under Part D, and none of the supplies or equipment are covered under Part D.

Currently, NHIA is working with CMS to resolve a wide spectrum of coverage, operational and logistical issues regarding home infusion therapy under Part D. While some progress has been made, the definitional issues continue to present significant problems. It is clear that adding to this muddled policy mix a new payment scheme would unnecessarily complicate an already complex and challenging situation.

Summary of Concerns and Issues regarding Home Infusion Therapy and Competitive Bidding

- Home infusion therapy is extremely service-intensive, and is perhaps the most invasive therapy covered by Medicare Part B; as such, it is a poor candidate for competitive bidding generally, and especially in the early stages of the competitive bidding program.
- Extremely complex definitional and coordination issues between Part B and Part D coverage for infusion therapy continue, and subjecting the Part B portion of infusion therapy coverage to competitive bidding would present needless logistical, operational and policy challenges for the Medicare program, the beneficiaries, physicians and discharge planners, and infusion pharmacies.
- The level of Medicare expenditures for DME infusion pumps and related drugs appears to be seriously over-inflated in the preamble to the proposed rule because CMS includes in the calculation (1) insulin and insulin pumps (2) drugs that are subject to exclusive [limited?] distribution agreements, and (3) drugs that are provided to the most severely compromised patients and which require a particular level of experience and expertise.
- The rate of growth of Medicare expenditures for DME pumps and related drugs was less than nine percent from 2003 to 2004, once we subtract the expenditures attributable to the three categories listed above.
- Home infusion therapy was never tested in the demonstration projects.
- There are no relevant studies and reports indicating that Medicare overpays for home infusion therapy under Part B; in fact, Congress exempted home infusion therapy from the average sales price methodology because of concerns that it would lower payment levels for home infusion therapy to a level that would impair access to quality care.

Necessary Steps Prior to Subjecting Home Infusion Therapy to the Competitive Acquisition Program

As indicated above, we believe Part B infusion therapy should not be subjected to competitive bidding until CMS can be confident that Medicare beneficiaries will have access to safe and quality care. Competitive bidding should be tested on less service-intensive areas before it is attempted with home infusion. In addition, the Part B and Part D coverage issues must be resolved. The best means of resolving these issues is to consolidate Medicare outpatient coverage of home infusion therapy under Part B.
Enteral Nutrition

Enteral nutrition involves the provision of nutrients by tube into the patient’s stomach or intestine. It is appropriate for patients whose lower gastrointestinal tract functions normally but who are unable to swallow, who have a gastric obstruction or who cannot otherwise ingest adequate amounts of food and fluids by mouth. Medicare Part B covers enteral nutrition formulas, supplies and equipment under the prosthetic device benefit for patients for whom enteral nutrition is necessary to maintain weight and strength commensurate with their general condition.

At this point, we do not believe enteral nutrition’s inclusion in the first phase of the competitive bidding program in 2007 would make significant progress towards CMS’ goals, and instead would present costly and complicated administrative challenges for CMS and its contractors. As explained below, enteral nutrition presents some of the most challenging obstacles for inclusion in the competitive bidding program, and we believe it would be an odd selection for the competitive bidding program to begin with in light of CMS’ objective of getting off to a successful start of this enormously complex program. We support the comments and the position of the National Alliance for Infusion Therapy on the issues pertaining to enteral nutrition, as set out below.

Factors Determining Product Selection

We will address each of these factors’ application to enteral nutrition.

I. Level of Medicare Expenditures

Enteral nutrition is listed in the proposed rule as fourth in total Medicare expenditures for Part B items for 2003. That number, however, is seriously misleading, since enteral nutrition is not a monolithic therapy provided in one setting. Rather, enteral nutrition, for policy purposes, should be divided into three parts:

1. Enteral nutrition provided to residents in long-term care (LTC) facilities;
2. Enteral nutrition provided in the home to patients who also qualify for the home health benefit; and
3. Enteral nutrition provided in the home to patients who do not qualify for the home health benefit.

Historically, a clear majority of Medicare Part B enteral patients are residents of long term care facilities. The percentage of enteral patients who are in LTC facilities increased from 2003 to 2004 to approximately 56 percent, based on the data described below. This fact is extremely relevant to CMS’ ultimate decision of whether to include enteral nutrition in the 2007 phase of competitive bidding. Based on our involvement with CMS in the development of the new Part B quality standards, we understand that the enteral-specific quality standards will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients.
Thus, enteral patients in long term care facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards on enteral nutrition.

Similarly, we understand that those enteral patients qualifying for the home health benefit are and will continue to be treated pursuant to the home health conditions of participation, not the enteral-specific Part B standards. Thus, the only segment of the enteral patient population who will be subject to the Part B enteral-specific quality standards are the home care patients who do not qualify for the home health benefit, a distinct minority of the Medicare enteral patient population. That small segment of the population does not involve Medicare expenditures anywhere near the top ten items of Part B expenditures.

II. Rate of Growth

Our analysis of enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition are far from skyrocketing. The rate of growth of Medicare allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were $20,624,897 less than they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS’ product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

III. Demonstration Project Experience

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS’ Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. Importantly, enteral nutrition was removed from that demonstration after the first phase of the project. CMS indicated that it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not well suited for competitive acquisition. Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

Importantly, enteral nutrition was the only therapy in the demonstrations where the majority of patients are in a setting other than the home. Competitive bidding clearly was designed by Congress with the home care patient in mind, a concept that the long term care
component of enteral nutrition would greatly complicate. We address this issue in greater detail in the section below about long term care facilities.

IV. Studies and Reports

The Office of Inspector General ("OIG") has issued many reports over the years about a wide array of product categories. A number of these studies were not written, or designed, to reflect all of the issues faced by policymakers on a particular subject. Instead, they were focused largely on a narrow issue or a small subset of issues, and as a result the reports often reflect a skewed perspective of (1) the particular problem and (2) the suggested solution to that problem.

This clearly has been the case with respect to OIG reports about enteral nutrition. A number of OIG reports about enteral nutrition contain estimates about supplier acquisition costs for enteral formulas, supplies and equipment, and compares those acquisition costs with Medicare payment rates. The OIG often describes the gap between the acquisition costs and payment rates as “waste” or “abuse”, despite the fact that the OIG has never focused on -

- The services and functions required of enteral nutrition suppliers to provide good quality care,
- The costs associated with these services and functions, or
- If payment rates are limited to the acquisition costs of items and equipment, then no supplier will be able to remain in business to provide enteral nutrition to Medicare beneficiaries.

Since policymakers are aware that enteral nutrition involves more than the delivery of formulas, supplies and equipment to beneficiaries, as most recently evidenced by the issuance of quality standards in this area, OIG reports such as the ones described above have limited value to CMS as a foundation for decision-making. Despite the clear limitations of the OIG reports on enteral nutrition as well as their seriously misleading conclusions, CMS indicated in the proposed rule that it wants to include these type of reports in its analysis of what product categories are best suited for inclusion in the competitive bidding program. We understand that CMS cannot simply ignore OIG reports, but we do urge CMS to place such reports in the proper context and determine whether their findings are supported by other sources of information. In the case of enteral nutrition, we believe you will find that the reports are largely inaccurate portrayals of what is involved in the provision of enteral nutrition and the costs associated with such therapy.

If CMS wishes to use outside sources to gather information about enteral nutrition functions and costs, we urge CMS to consult with the American Society for Parenteral and Enteral Nutrition (ASPEN), the clinical society for physicians, nurses, dietitians and pharmacists involved in the provision of enteral nutrition. ASPEN has developed quality guidelines as to the functions and services required for enteral nutrition. Likewise, we suggest CMS consult with the Joint Commission on the Accreditation of Healthcare Organizations and other accrediting organizations as to their perspective on what is involved in the provision of enteral nutrition.
In addition, the OIG studies could not have reflected the costs associated with accreditation, either in terms of the administrative costs of seeking and maintaining accreditation or the costs of complying with the new Part B quality standards that are the bases of accreditation. In light of this clear discrepancy, we urge CMS not to rely heavily on OIG reports in determining product selection for the competitive bidding program.

The reasons for excluding enteral nutrition from the first phase of the competitive bidding program are not limited to the criteria set out above. There are important other bases for omitting enteral from the 2007 portion of competitive bidding, including the following:

*Enteral Patients in Long Term Care Facilities*

As indicated above, most enteral nutrition is provided in nursing facilities, which presents issues that go far beyond the scope of the competitive acquisition program. It is apparent that CMS and its contractors will be burdened with numerous complex issues to implement the competitive acquisition program even in the most basic manner possible. Attempting to use competitive acquisition for products used in long term care facilities raise a whole host of issues involving access and choice that are not easily resolvable, especially in the immediate timeframe.

Nursing facilities have a special relationship with their residents. In most instances, the facility is the resident’s home. The nursing facilities are responsible for coordinating the work of an array of clinicians, providers and suppliers to meet patient health care needs, and they are held accountable for the quality of these services. Nursing homes must meet detailed conditions of participation to participate in the Medicare and Medicaid programs as well as a wide array of additional quality standards. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism.

For these reasons, most nursing facilities will be extremely concerned if they are forced to admit unfamiliar suppliers into their facilities to provide services, supplies, and equipment to their residents. Nursing facilities must be able to select the suppliers that the facilities believe can best enable them to meet resident needs and comply with applicable standards. The competitive bidding program would interfere with their ability to make these decisions, and potentially interrupt ongoing relationships that have worked to the benefit of their residents.

CMS’ demonstration projects did not test a model of competitive bidding that involved long-term care facilities. This is extremely important, because the proposed rule reflects an overly simplistic view of how long term care facilities operate and how they could fit into the competitive bidding program. We are concerned that the proposed rule appears to reflect a view that a nursing home is simply a supplier that does not have to travel to treat its patients. The only recognition that a nursing home is different in any respect is the provision that a nursing home can limit its participation in the competitive bidding program to treating its own residents. What is surprising is the clear implication that a nursing home actually has to be a winning bidder just to treat its own residents. Residents in nursing homes usually are more impaired than home care patients and require a different regimen of care. Primarily for that reason, it would not be a fair
or accurate process to combine nursing home bids with home care bids for a particular products category.

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and should not be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

We do not understand how there can be fair and responsible competitive bidding when there are at play different quality standards, different settings of care, and different patient needs. As explained below in the section on competitive pricing principles, competitive bidding requires bidders to have to meet the same requirements in the same context. The nursing home component flies in the face of this principle. With all respect, we do not believe CMS has considered the differences and particular problems the nursing home setting brings to the competitive bidding program. We urge CMS to refrain from selecting products for inclusion in competitive bidding if, as with enteral nutrition, most of the Medicare market for those products is in the long term care setting.

**Application of Quality Standards**

The competitive bidding program is predicated in large part on the application of the Part B quality standards and the requirement that every participating supplier be accredited in accordance with the accreditation provisions of the proposed rule. This is an important component of the overall scheme of the competitive bidding program, wherein bidders will have similar costs and will benefit from a generally level playing field. That makes perfect sense – again, except with regard to enteral nutrition.

For the enteral patient population, there will not be one set of quality standards – there will be three sets of standards: the conditions of participation for long term care facilities; the conditions of participation for home health agencies; and the quality standards under development in connection with the competitive bidding program. This creates a unique problem for enteral nutrition.

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. Likewise, enteral nutrition is provided to homecare patients by suppliers that focus solely on the homecare market. In other words, the quality standards and the enteral suppliers in the homecare setting will be significantly different from the quality standards and enteral suppliers in the long term care setting. The application of the home health conditions of participation to those homecare enteral patients who qualify for the home health benefit only further complicates an already complicated situation.

Thus, it would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the
settings of care differ. On the other hand, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

**Payment Basis: Enteral Nutrition Pumps**

Under current payment policy, monthly rental payments for enteral pumps were calculated originally on the basis of the purchase price for the particular type of pump. Once the purchase price was determined, the monthly rental payments were set at 10% of that purchase price up to a maximum of 15 months. This has been different from items in the DME capped rental category, wherein monthly rental reimbursement for capped rental items has been 10% of the purchase price for the first 3 months and then it is reduced to 7.5% of the purchase price for each of the remaining months of coverage.

However, the proposed rule would reduce monthly rental payments for enteral pumps under the competitive bidding program for the months 4-15 to 7.5% of the purchase price. In other words, under the competitive bidding program, rental payments for enteral pumps would be determined as if enteral pumps were capped rental items.

Enteral pumps are not capped rental items. Rather, they are covered under the prosthetic device benefit and reimbursed under a fee schedule specifically tailored for enteral nutrition. Further, Congress explicitly rejected an attempt by CMS in 1989 to put enteral pumps in the DME capped rental category. CMS’ proposal for the competitive bidding program would effectively negate an explicit act of Congress. If enteral pumps ultimately are to be included in the competitive bidding program, they should be reimbursed on the same basis as they are now – 10% of the purchase price for up to 15 months.

There does not appear to be any policy basis for CMS’ proposal regarding enteral pumps, other than simply to further reduce payments for these items. That objective alone, we submit, is not enough to counter Congress’ intent in keeping enteral pumps separate from the DME regulatory scheme.

**Payment Basis: Grandfathering**

The proposed rule does not extend grandfathering provisions to enteral nutrition. Instead, it limits all grandfathering protections to DME and oxygen items. We understand that the statute requires grandfathering only for those items, but we believe the statute does not prohibit CMS from extending grandfathering protections to other products that are subject to the competitive acquisition program in the interests of program efficiency.

The policy bases for grandfathering DME and oxygen items apply with equal force to enteral nutrition. Beneficiaries already on service often develop trusting relationships with their
Enteral suppliers, and many would prefer to continue that relationship for the entire course of their therapy. In addition, the responsibility for servicing and maintaining enteral pumps would be an important issue for the new contract enteral supplier. The contract supplier will be liable for the servicing and maintenance of enteral pumps which it did not provide to the beneficiaries.

Enteral pumps are not capped rental items, but the duration of the rental payments for such pumps is limited to 15 months. At the very least, it would be sensible to permit the “old” enteral supplier to continue with an enteral patient until the 15 month rental period elapses.

**Necessary Steps Prior to Subjecting Enteral Nutrition to Competitive Bidding Program**

As indicated above, we are strongly urging CMS to delay application of competitive bidding to enteral nutrition until a later phase of the program. The issues that we have raised regarding nursing homes, quality standards and operational issues peculiar to enteral nutrition make it clear to us that these issues cannot be resolved in the short timeframe leading up to the 2007 phase of the competitive bidding program. We recommend instead that CMS and representatives of the various enteral nutrition stakeholders work together to resolve the many issues that pertain to enteral nutrition.

In particular, we suggest the following actions:

- Clarify the different requirements and obligations specific to enteral suppliers regarding nursing homes and their residents
- Integrate the Part B product-specific standards applicable to enteral nutrition with the nursing home quality standards
- Clarify the different requirements and obligations specific to enteral suppliers regarding home health agencies and their patients
- Integrate the Part B enteral standards with the home health quality standards

**Competitive Bidding Areas**

The proposed rule provides CMS with the authority to designate competitive bidding areas in the initial phase of the competitive acquisition program as extending beyond the boundaries of the selected metropolitan statistical areas (MSAs). We do not believe this proposal is consistent with the statute.

Section 1847(a)(1)(B) of the Act specifically provides that CMS is to phase in the competitive bidding program so that competition occurs in the 10 largest MSAs in 2007 and 80 of the largest MSAs in 2009. The statute authorizes expansion of the competitive acquisition program to areas beyond MSAs only after 2009. Section 1847(a)(1)(B)(i)(III).

If Congress intended competitive bidding areas to include areas outside of the MSAs in 2007 and 2009, it would have authorized CMS to include those areas as it did for expansions occurring after 2009. It did not do so. The fact that Congress was so specific in its language on
this point makes it clear that CMS was not authorized to venture beyond the borders of MSAs in the 2007 phase of the program.

In addition to health policy issues raised above, we have several concerns regarding the application of basic federal procurement principles to the proposed competitive acquisition program, which we summarize below.

**Competitive Pricing Issues**

The Medicare Modernization Act ("MMA") reflects a clear Congressional intent that, to the maximum extent practicable, CMS is to utilize the concept of competitive pricing in its implementation of the competitive bidding program. The expression of this Congressional intent first appears in Section 302 (b) of the MMA which begins by changing the heading of Section 1847(a) of the Act to read: “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES…. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.” The provision then directs the Secretary to “establish and implement programs under which competitive acquisition areas are established...for the furnishing...of competitively priced items and services...” (italics added) and provides that “[p]ayment under this part for competitively priced items and services...shall be based on bids submitted and accepted under this section for such items and services.” (italics added.) Sections 1847 (a) (1) (A), (b) (5)

The term “competition” is defined as “a market condition in which a large number of independent buyers and sellers compete for identical commodities...” Webster’s Third International Dictionary (1976) A price is “the amount of money given or set as the amount to be give as a consideration for the sale of a specified thing.” Black’s Law Dictionary, Sixth Edition (1991) at 1188. (italics added.) “Pricing means the process of establishing a reasonable amount or amounts to be paid for supplies or services.” Federal Acquisition Regulation (FAR) 2.101. In light of these definitions, it appears that when Congress directed CMS to establish a program that entails “furnishing...of competitively priced items and services” it understood that the constituent elements of the program would include: a number of independent sellers who can furnish specified items or services that are identical as to function and who can offer to sell the items or services at a specified amount or price.

CMS has correctly chosen to characterize the Congressionally mandated use of competitive pricing as a program of “competitive bidding” for DMEPOS. The Government Accountability Office has long considered issues relating to competitive bids and, in doing so, has aptly described the characteristics of an invitation for bids, stating that it:

“...must contain specifications that are sufficiently descriptive in language to permit full and open competition, and to permit evaluation of bids upon a common basis. ...the invitation must provide objectively determinable standards against which the bids can be evaluated on an equal basis to determine the acceptability of the low bid” McBride and Tuohy, Government Contracts, Section
Thus, competitive pricing and its fraternal twin competitive bidding both require that those competing to sell an item or service to the government must be given the opportunity to make their bids, submit their offers or propose their prices on the same item or service and under conditions that allow evaluation of their bids, offers or prices on an equal basis whether the outcome is to be a single award or, as is the case here, awards to multiple bidders.

With that as background, we believe the application of these competitive pricing principles raises important concerns regarding the proposed competitive bidding program.

First, in addition to the policy and fairness issues we described earlier in these comments, we believe the application of competitive bidding to enteral nutrition would be counter to basic competitive pricing principles. The application of different quality standards, and the existence of different markets within the enteral nutrition area, means that the competition for contracts could not be on an equal basis. Enteral nutrition suppliers that focus solely on the nursing home market will have a different business and cost structure from enteral nutrition suppliers that focus solely on the homecare market. A competitive bidding program that combines the two types of enteral suppliers into one bidding group clearly is inconsistent with competition on an equal basis.

Secondly, Section 414.414(h)(1) of the proposed rule provides that “Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program.” In order to select additional contractors, CMS plans to use bids previously submitted by bidders in the specific product category for which additional contract suppliers are needed to make award. CMS plans to offer award first to the disappointed bidder whose composite bid is the first composite bid above the pivotal bid for that product category.

This is an inappropriate method for the acquisition of additional contractors following award. First, by awarding contracts after award without competition, CMS would violate the clear language of the statute, which requires that CMS conduct a competition for the award of any contracts for the items specified by the statute. The statute states: “[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.” Sec. 1847(b)(1) of the Act.) A post-award contract award to the next-in-line disappointed bidder who participated in the initial competition is not a competitive acquisition. It is not a continuation of the original competition. It is a sole-source acquisition. (See 41 U.S.C.A. § 253(a),(c) (West 1987 and Supp. 2006); see 48 C.F.R. 2.101 for the definition of sole source acquisition.) Sole-source awards to contractors for items and services within competitive acquisition areas are not authorized by the statute.
Gap-Filling Proposal

CMS proposes to modify its current gap-filling procedures and instead use far more subjective criteria in developing payment levels for new products and for new HCPCs. We agree that the current gap-filling practices should be revised – they are not well understood and probably result in payment levels that are significantly lower than the payment levels found in the private sector.

That said, we must strongly oppose the particular modification proposed by CMS. CMS simply listed a number of general factors for determining gap filling amounts, without any indication how they would be used. CMS is proposing to give itself what appears to be virtually unfettered authority to choose and apply payment criteria for any new product. Perhaps of greater concern is CMS’ intention to apply this broad authority to new codes. It would appear that CMS could trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. Section 1842(b)(8) of the Act. This so-called “inherent reasonableness” authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS’ inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15 percent more or less than a reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including

1. The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.
2. What entities would be affected, such as classes of providers or suppliers and beneficiaries.

3. How significantly would these entities be affected.

4. How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

Additional factors apply if CMS seeks to modify payment levels by more than 15% in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to
adjust payment rates. We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority.

Thus, the proposed rule would act to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS could create a new HCPCS category, use the vague "functional technology assessment" to compare older, similar products already on the market to newer products and bundle all of these into the new HCPCS codes. CMS could then use the revised "gap filling" process to reprice the existing products and new products establishing what amounts to a revised payment. Since there is already a statutory avenue for addressing excessive or deficient payment under the "inherent reasonableness" methodology, the new regulations would at best be duplicative of these provisions. At worst, they would act as a contravention of existing law.

There may well be a need for the development of new codes in the future, and we are not suggesting that the current coding structure is somehow untouchable. We strongly believe, however, that if and when coding modifications must occur there must be a far more formal, transparent and inclusive process for determining reimbursement for the items in the new codes than is proposed in this regulation.

Thank you for the opportunity to comment on the important proposed rule. If you have any questions or desire additional information from NHIA, please contact me at 703-838-2658 or lorrie.kaplan@nhianet.org.

Sincerely,

Lorrie Kline Kaplan
Executive Director

Attachment: Appendix A: Infusion Therapy Services
Appendix A

Infusion Therapy Services

There are a number of necessary functions and costs associated with the safe and effective administration of home infusion drug therapy. These important functions and costs, detailed below, are consistent with the well-established standards of care recognized by national accrediting organizations, as well as common practices for patients under both private and public health insurance plans. (See Appendices A, B, and C, summary statements provided by the three national accrediting organizations offering accreditation of home infusion therapy service providers, the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Commission for Health Care, and the Community Health Accreditation Program.

In addition, for a quick visual presentation of home infusion services and operations, see the National Home Infusion Association’s online virtual tour which begins at http://www.nhianet.org/virtualtour/slide1.htm.

A. Direct Patient Services

Initial Patient Evaluation and Assessment. Initial patient evaluation is an important component of infusion therapy. At initial intake, the pharmacy must collect information on the clinical status and medical history of the patient, examine the physician’s orders and laboratory reports, gather information on the cognitive and psychosocial status of the patient, and determine the patient’s appropriateness for home therapy.

After the patient is accepted for service, comprehensive assessment activities include a complete physical assessment of the patient, an assessment of the appropriateness of the home environment for home infusion therapy, a review of concurrent oral prescription and over the counter medications, an evaluation of the patient’s ability to learn self-administration, and a review of the medical history. Admission procedures include patient and family teaching for mechanical and disposable equipment use, medication storage and handling, emergency procedures, vascular device management and the recognition and reporting of adverse drug reactions and other infusion related complications.

Development and Implementation of the Patient Care Plan. The home infusion pharmacy is the primary entity responsible for the development and implementation of the multidisciplinary care plan. Care planning activities consider actual or potential drug or equipment related problems, therapy monitoring with specific goals, coordination of activities with other providers and provide ongoing patient monitoring and reassessment activities to continually assess for response to treatment, drug complications, adverse reactions, and patient compliance. The infusion pharmacy must also communicate and coordinate the care plan with the physician, patient, patient’s family, and other health care providers.
Compounding and Dispensing of Infusion Medications and Equipment. Home infusion drugs and solutions must be prepared under environmentally controlled conditions, as mandated by various regulatory and accreditation agencies. Sterile admixtures are prepared in a clean air environment, using aseptic techniques. The compounding room must be designed and maintained appropriately to prevent contamination. The specifications of home infusion compounding rooms typically exceed those of hospital environments because the compounded products must be capable of remaining sterile for longer periods of time than is required in the inpatient setting whereas infusion therapies are usually administered within 24 hours of preparation. Final compounded products are subject to routine quality control procedures designed to ensure the accuracy of the preparations, product integrity, stability, and sterility. Depending on the pharmacy’s volume of business and applicable legal restrictions, trained pharmacy technicians may prepare drugs under a pharmacist’s supervision.

Each patient’s prescription is filled in quantities and at intervals sufficient for continuous service. Frequency of drug preparation depends on several factors, including expected duration of treatment, frequency of dose administration, home delivery schedules, drug stability or shelf-life, and the patient’s clinical condition. The average time required to compound, dispense, assemble, and package a patient’s order depends, in part, on the number of doses in an order, the quantity of each dose, the number of compounded doses per delivery, the volume and number of ingredients and the complexity of compounding. Time and motion studies conducted by the University of Texas College of Pharmacy document the variability of these activities by therapy.[1]

The ancillary supplies and equipment necessary to administer the therapy must be selected and packaged for delivery to the patient’s home. Infusion therapy-related supplies are uniquely tailored to the individual patient based on the patient’s vascular access device, type of infusion delivery device and the patient’s ability to perform self-administration.

Ongoing Clinical Monitoring. Throughout the course of therapy, and particularly after a nursing visit, the pharmacist reviews an infusion patient’s clinical information, discusses the findings with the attending physician, assesses the continuing appropriateness of the current medication schedule, participates in multidisciplinary patient care conferences to examine the patient’s progress and to establish future goals, and communicates with the patient’s other caregivers regarding the patient’s compliance and progress.

On-Call Services. Offering continuous, round-the-clock on-call services (24 hours a day, seven days a week) is a standard of practice for home infusion providers. This practice reflects the acute need for the continuous availability of a qualified home infusion pharmacist and nurse to support the complex therapies and infusion equipment that these patients require. Calls may include new or changed orders from the nurse or physician, questions about the medication from the patient or the nurse, troubleshooting the pump, concerns about why a delivery has not arrived, a possible adverse drug reaction, vascular access issues, or need for medication or supplies. The on-call pharmacist often triages the call, then addresses the problem or refers the call to the patient’s physician or home care nurse.
Patient Discharge Services. Patient discharge services include communication with all health care providers involved with the case and the closing of the medical record. Clinical outcome data, patient perception data, and the documentation of staff is reviewed and collected as part of the ongoing quality management activities required by state regulations and accreditation standards.

B. Administrative and Support Services
There are significant direct and indirect administrative and support services that impact the quality of patient care. Home infusion therapy cannot be coordinated and delivered effectively without adequate administrative and support personnel. Many of these requirements are established by licensing boards, accrediting bodies, private insurance plans, and federal and state health programs. Other activities are simply part of managing and operating any health care entity. Examples of administrative and support services include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing and collections, medical waste management, personnel management, inventory control, orientation programs for new employees, and clinical development and education programs for management and staff.

Accreditation, for example, is an indirect cost that affects the quality of care delivered by home care pharmacies. Accredited companies must meet quality standards for patient care and business functions to maintain accreditation (see Appendices A, B, and C). Accreditation offers the public the assurance that an accredited entity meets or exceeds an objectively verifiable standard of care. It will be a setback for Medicare beneficiaries if Medicare reimbursement does not adequately reimburse providers and suppliers for the cost of meeting quality standards. In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements.

Home care pharmacies also incur significant costs in complying with Medicare program rules, especially those pertaining to billing and documentation. These include, among others, the following:

Accumulating documentation to support claims for services
Preparation of claims
Communication with physicians regarding completion of certificates of medical necessity and other documents required by the program from physicians
Communication with carriers regarding claims and documentation
Participating in medical review process with carriers on particular claims
Delays in payment from the program
Preparing for and filing appeals to the carrier and Social Security Administration