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Need to Overhaul Costly Payment System for Medical Equipment and Supplies

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The Honorable Charles E. Grassley
Chairman
The Honorable John B. Breaux
Ranking Minority Member
Special Committee on Aging
United States Senate

In 1996, Medicare's Supplementary Medical Insurance (Medicare part B) paid over $4.6 billion for medical equipment, supplies, prosthetics, and orthotics—products referred to as durable medical equipment (DME) in this report.[1] Medicare part B pays for DME for patients who live at home or in long-term care facilities, such as nursing homes.[2] Our prior studies and a report by the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) have documented that Medicare pays higher than market rates for some items.[3] The Health Care Financing Administration (HCFA) agreed that Medicare pays too much for some products but said that the "inherent reasonableness" review process[4] it was required by statute to use hindered HCFA's efforts to address overpricing. This process was too slow and cumbersome to be of practical use. The process involved, for example, a detailed notice and comment rulemaking procedure that required clearance by the Administrator of HCFA, the Secretary of HHS, and the Director of the Office of Management and Budget.

At your request, we reviewed Medicare payments for commonly purchased, off-the-shelf DME such as walkers, catheters, glucose test strips, and orthotic braces. On June 17, 1997, we provided you with an interim

[1]The Medicare payment represents the fee schedule allowances for these products. Medicare pays 80 percent of the allowance or the amount billed on the claim, whichever is lower; Medicare beneficiaries are responsible for the remaining 20 percent. Medicare DME payments for products not covered by fee schedules, such as drugs and enteral and parenteral products used with DME, are not included in the $4.6 billion or discussed in this report.

[2]Medicare part A generally pays for medical equipment and supplies provided during in-patient stays in acute care hospitals and skilled nursing facilities. However, Medicare part B pays for orthotic devices for patients in skilled nursing facilities as well as for patients who live at home or in long-term care facilities.

[3]See Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements (GAO/HEHS-95-171, Aug. 8, 1995), Medicare Spending: Modern Management Strategies Needed to Curb Billions in Unnecessary Payments (GAO/HEHS-95-210, Sept. 19, 1995), and Durable Medical Equipment - Review of Medicare Payments for Home Blood Glucose Monitors, HHS OIG, A-09-92-00034 (Washington, D.C.: Dec. 1992).

[4]42 U.S.C. 1395m(a)(10) and 1395u(b)(8) and (9) (1994).

report,[5] and the Congress subsequently included provisions in the Balanced Budget Act of 1997 (BBA) giving HCFA the authority to more quickly adjust Medicare's fee schedule allowances by up to 15 percent per year. This report focuses on problems HCFA must overcome to effectively use its new authority. More specifically, this report discusses the need to (1) better identify products billed to Medicare and (2) bring Medicare fees more in line with current marketplace prices.

To address these issues we researched Medicare laws and regulations and met with officials from HCFA and its contractors to determine how they set the Medicare fee schedule allowances. We explored ways to better identify products billed to Medicare by obtaining information on universal product numbering systems for medical products from the Department of Defense; associations representing medical equipment suppliers, distributors, and manufacturers; a private consultant; and two standards-setting organizations. We also evaluated Medicare payments for selected DME by collecting and analyzing information on product pricing, distribution channels, and purchasing practices from manufacturers, suppliers, and industry groups.

We performed our field work between March 1996 and February 1998 in accordance with generally accepted government auditing standards, except that we did not audit the cost and pricing information obtained from suppliers; however, we noted that the cost and pricing information we obtained was fairly consistent among the suppliers we contacted. Appendix I provides additional details on our scope and methodology and a listing of the types of items included in our review.

Results in Brief

There are two underlying problems with Medicare's DME payment system. First, HCFA does not know specifically what products Medicare is paying for when its contractors process claims for DME. The only product identifiers on the claims are HCFA billing codes that cover a broad range of product types, quality, and market prices. For example, we determined that one Medicare billing code is used for more than 200 different urological catheters. The wholesale prices of these catheters range from about $1 to about $18, but information we gathered from some suppliers showed that the catheters they most frequently provide are also the least expensive—about $1. Yet, the Medicare fee schedule allowance for all the catheters in this group is about $11. Without more specific product

[5]Medicare: Problems Affecting HCFA's Ability to Set Appropriate Reimbursement Rates for Medical Equipment and Supplies (GAO/HEHS-97-157R, June 17, 1997).

identifiers on Medicare claims, HCFA cannot routinely determine what products are being billed under each billing code, which products should be grouped together under the same billing code, or whether the Medicare payment for all the products grouped under a billing code is reasonable. The health care industry is increasingly using bar-coded, product-specific identifiers for medical products, but HCFA does not have any plans to require these identifiers on Medicare claims.

The second underlying problem with Medicare's DME payment system is that the fee schedule allowances for DME are often out of line with current market prices. Most Medicare fees are based on historical supplier charges that are updated using the consumer price index. The BBA gave HHS the authority to use a streamlined "inherent reasonableness" review process to adjust Medicare fees by as much as 15 percent in one year. This streamlined authority should help HCFA bring the historical, charge-based fees into line with marketplace prices, but some obstacles remain. HCFA and its contractors do not have sufficient, current product and pricing data for the thousands of DME items covered by Medicare. For example, some new products that use improved technology and materials are not even listed in the fee schedule—some hand/wrist braces are now self-adjustable and available as off-the-shelf products, but the current fee schedule lists only more expensive, custom-fabricated hand/wrist braces. Another obstacle to appropriate reimbursement is that the fee schedule allowances are the same for individuals and for large institutional suppliers, even though large suppliers buy at substantial discounts. For example, over a 12-month period one large supplier billed Medicare for over 37,200 catheters; the supplier's weighted average cost for the catheters was less than $1 each, but Medicare paid the supplier almost $12 per catheter. Although the BBA gives HHS the authority to more quickly adjust fees, addressing these underlying problems may require additional statutory authority; therefore, we have identified some options for congressional consideration.

Background

Medicare part B pays for most medical equipment and supplies using a fee schedule system. The fee schedules specify a Medicare allowance for each of about 1,900 groups of products, and each product group is identified by a HCFA Common Procedure Coding System (HCPCS) code. All the products grouped under a HCPCS code have the same fee schedule allowance and are intended to be similar items.[6] When suppliers bill Medicare, they use the

[6]Under current policy, Medicare does not pay extra for products that have convenience features but are equivalent to less expensive products.

HCPCS code they believe best describes the specific product provided to the patient. Suppliers and manufacturers may also petition HCFA to establish new HCPCS codes for products they believe are not adequately described by existing codes.

Various types of DME are covered by different fee schedules. For inexpensive, routinely purchased items, such as walkers, canes, glucose test strips, and ostomy and urological products, Medicare has a separate fee schedule for each state. These fee schedules are based on the average charges that Medicare allowed in each state in 1986 and 1987. To reduce variation in Medicare fees among the states, the state fees are subject to national floors and ceilings. The national floor for each HCPCS code is 85 percent of the median of all the state fees, and the ceiling is the median of all state fees.[7] The state fees are usually adjusted annually for inflation using the consumer price index, but the BBA amended Medicare law to freeze the fee schedule allowances for medical equipment and supplies for 5 years, beginning in 1998.

For orthotic and prosthetic devices, including off-the-shelf items that do not require custom fittings and adjustments, Medicare uses 10 regional fee schedules. Each regional fee schedule is based on a weighted average of the charges Medicare allowed in 1986 and 1987 for each state in the region. Similar to the fee schedule for inexpensive and routinely purchased items, the orthotic and prosthetic fee schedules are subject to national floors and ceilings. The national floor for each HCPCS code is 90 percent of the average of all regional fees, and the ceiling is 120 percent of the average. The orthotic and prosthetic fee schedules are also usually adjusted annually for inflation using the consumer price index, but the BBA amended Medicare law to limit the increases to 1 percent per year for 5 years, beginning in 1998.

Four HCFA contractors, called durable medical equipment regional carriers (DMERC), process and pay claims for medical equipment and supplies. A fifth contractor is responsible for analyzing DME claims and answering questions from the carriers and suppliers regarding use of the HCPCS codes.

[7]Under 42 U.S.C. 1395m(a)(10)(A), Alaska, Hawaii, and Puerto Rico are excluded from these national payment limits.

Claims Do Not Adequately Identify Products Billed to Medicare

HCFA does not know specifically what Medicare is paying for when its contractors process claims for DME. We identified the products billed under some HCPCS codes and found that the Medicare fee schedule allowance was appropriate for a few of the products but grossly excessive for many of the products billed under the same code. Without more specific product identifiers on Medicare claims, HCFA cannot systematically determine if the fee schedule allowances are appropriate.

HCPCS Codes Are Not Sufficient for Medicare Reimbursement

Products that differ widely in properties, use, performance, and price are being billed under the same HCPCS code and reimbursed at the same fee schedule allowance. For example, more than 200 short-term, medium-term, and long-term catheters are billed under one HCPCS code for latex Foley catheters.[8] According to a major manufacturer of Foley catheters, specialized coatings affect the durability, function, and price of the catheters within this group. The wholesale prices of these catheters range from about $1 for a short-term catheter to almost $18 for a long-term catheter. The 1997 Medicare fee schedule allowance for all the catheters in this group was between $9.95 (the national floor) and $11.70 (the national ceiling).

Since Medicare pays the same fee for all the products billed under the same HCPCS code, suppliers have a financial incentive to provide patients the least costly product covered by the code—they can bill Medicare the full fee schedule allowance regardless of the product provided. For the latex Foley catheters discussed previously, information we gathered from some suppliers showed that the basic short-term catheter, which wholesales for about $1, was the most commonly provided catheter. Since Medicare claims do not identify specific products, HCFA would have to undertake a special study to discover, as we did, that suppliers are usually providing $1 catheters for products with a Medicare fee schedule allowance of about $10 to $12.

Without product-specific identifiers on Medicare claims forms, HCFA cannot effectively review the mix of products billed under a HCPCS code to (1) identify the need to regroup similar products under existing or new billing codes, (2) adjust the code descriptions and the guidance to suppliers advising them which HCPCS codes to bill, (3) identify claims billed under inappropriate HCPCS codes, and (4) adjust the fee schedule

[8]A latex Foley catheter is typically billed under HCPCS code A4338 (indwelling catheter; Foley type; two-way latex with a coating, such as Teflon, silicone, silicone elastomer, or hydrophilic).

allowance for a HCPCS code so that it reflects the costs of the products covered by the code.

Product-Specific Codes Are Available to Better Identify Products

Universal product numbers (UPN) and associated bar codes are increasingly available to identify specific medical equipment and supplies, similar to the way universal product codes are used in supermarkets. Manufacturers can use bar codes for each product to identify characteristics such as the manufacturer, product type, model, size, and unit of packaging (for example, 10 per carton). Industry standards organizations have created two UPN formats for medical equipment and supplies: (1) an alphanumeric standard that provides very detailed product information and (2) an all-numeric standard that is more consistent with international coding standards. Both these UPN formats can be used interchangeably in automated claims-processing systems.

The Department of Defense and some hospital purchasing groups are already setting deadlines for their vendors to use UPNs as the standard product identification on all transactions involving medical equipment and supplies. UPNs will enable these government and private purchasers to develop standard product groups, track market prices, and use prudent purchasing methods—paying for medical equipment and supplies that meet quality standards at competitive market prices. Also, a state Medicaid agency is developing a claims processing system that would require UPNs on claims for medical supplies billed to the state.

If suppliers were required to include UPNs as well as HCPCS codes on Medicare claims, HCFA could routinely gather the information it needs to group similar products under the same HCPCS code and set an appropriate reimbursement rate for each code. For example, according to a product expert with a manufacturer of urological products, the HCPCS code used for latex Foley catheters is too broad and could be split into three separate codes and reimbursement rates—one each for short-term, medium-term, and long-term catheters. After implementing these adjustments, HCFA contractors could use their automated claims-processing systems to check the UPNs on claims and determine if suppliers are billing for these catheters under the appropriate HCPCS codes.

Section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended the Social Security Act to require the Secretary of HHS to adopt standards for the electronic exchange of health information.[9]

[9]42 U.S.C.A. 1320d-2 (West Supp. 1997).

These standards are expected to incorporate a medical product coding system. Although HCFA officials acknowledge the limitations of coding under HCPCS, HHS plans to designate HCPCS as the national standard to be implemented in the year 2000, based on the belief that this would be less disruptive to the health care industry. However, industry groups and suppliers we contacted said they find the HCPCS difficult to use, and industry surveys show that many manufacturers already label their products with UPNs and bar codes to track their inventories. Industry groups contend that Medicare, the nation's largest health care insurer, should be leading the effort to require the use of UPNs, especially since this coding system would enable HCFA to exercise better control over Medicare payments for medical equipment and supplies. HCFA officials said they are willing to consider implementing changes to the national coding standards after the year 2000, when the industry has had more time to consider a uniform coding approach for medical equipment and supplies.

Medicare Fees Do Not Reflect Current Market Prices or Discounts Obtained by Large Suppliers

Medicare's fee schedule allowances for DME are often out of line with current retail prices paid by individual beneficiaries and with competitive marketplace prices paid by large suppliers. Section 4316 of the BBA amended the Medicare law to permit HCFA to use a streamlined process to adjust fee schedule allowances up or down by as much as 15 percent in one year. This new authority can help HCFA bring the historical, charge-based fees into line with marketplace prices, but some obstacles remain: (1) HCFA and its contractors do not have sufficient current product or pricing data on the thousands of items covered by the DME fee schedule and (2) the fee schedule reimburses large suppliers who buy at volume discounts the same fee schedule allowances as individuals who buy single items at retail prices. A number of options are available for setting more appropriate reimbursement rates.

Medicare Fees Are Often out of Line With Current Prices

Since the current Medicare fee schedule is based on supplier charges that Medicare allowed in 1986 and 1987, some Medicare fees have little correlation with today's market prices for medical equipment and supplies. Competition has led many suppliers to increase their purchasing power and lower their product costs by consolidating with similar businesses or joining purchasing cooperatives. On the other hand, new products that use more expensive materials to better meet the needs of some patients may be more highly priced than the Medicare fee schedule allowances for those products. For example, a HCFA contractor found that in 1996

- the average retail price for an irrigation tray with bulb (HCPCS code A4320) was $2.83, while Medicare's 1996 floor and ceiling for the item were $4.20 and $4.94, respectively;
- the average retail price for an intermittent urinary catheter with straight tip (HCPCS code A4351) was $0.87, while Medicare's 1996 floor and ceiling for each item were $1.43 and $1.68, respectively; and
- the average retail price for a one-piece ostomy pouch (HCPCS code A5061) was $3.37, while Medicare's 1996 floor and ceiling for each item were $2.46 and $2.89, respectively.

Medicare payments for some orthotic devices are excessive because even though improved technology and materials have made some orthotics less costly, some of these less costly products are not listed in the Medicare fee schedule. Moldable plastic, velcro closures, and prefitted sizes have eliminated the need to individually design and fabricate many orthotic devices, but as the HHS OIG recently reported, even though orthotic devices are increasingly available off the shelf, the HCPCS codes still reflect the more costly, custom-fabricated products.[10] For example, a prefabricated, self-adjusting hand/wrist brace can be purchased from a supplier's catalog for $120, but the only similar item listed in the current Medicare fee schedule is a custom-fabricated brace with an allowance of up to $290.92. HCFA's contractors said that for items not listed in the fee schedule, suppliers should bill a "miscellaneous" HCPCS code and submit documentation describing the item. However, such claims must be processed manually, and the HHS OIG reported that the outdated fee schedule leads some suppliers to bill Medicare for these items using codes and allowances for the custom-fabricated orthotics.

Medicare Fees Do Not Reflect Volume Discounts Obtained by Large Suppliers

Medicare pays the same fees to individuals and to large institutional suppliers, even though large suppliers obtain substantial discounts. For example, information we obtained from one large nursing home supplier showed that over a 12-month period the supplier billed Medicare for over 37,200 latex Foley catheters. The supplier's weighted average cost for the catheters was less than $1 each, but Medicare's fee schedule allowance was between $9.95 and $11.70 for each catheter. The same supplier billed Medicare for 78,100 bedside drainage bags in a 12-month period. The supplier's weighted average cost was about $2.24 per bag, but Medicare's fee schedule allowance was between $7.65 and $9.00.

[10]See OIG report, Medicare Orthotics, OEI-02-95-00380 (Washington, D.C.: HHS, Oct. 9, 1997).

Suppliers who bill Medicare incur administrative costs in addition to product costs, but administrative costs do not account for the disparity between large suppliers' unit costs and Medicare's fee schedule allowances. Administrative costs are largely attributable to documenting the medical necessity for the initial claim; subsequent claims to reorder items for the same patient involve less time and cost. Suppliers have estimated that the average administrative cost for filing a Medicare claim for a reordered product is about $10. We did not verify that estimate, but it should be noted that suppliers typically include several related supplies on a single claim, and allocating the estimated $10 administrative cost among the three or four items would reduce the administrative cost to between $2.50 and $3.35 per item.

For some products a few large suppliers account for a substantial number of the claims paid by Medicare. For example, for one particular type of catheter, 10 suppliers accounted for almost 55 percent of the charges billed to Medicare between July 1, 1996, and September 30, 1996. For five other HCPCS codes in our study, 10 suppliers accounted for 24 percent or more of total allowed charges. These large suppliers include firms that billed Medicare directly for equipment and supplies provided to Medicare beneficiaries in nursing homes. As discussed in the next section, the amendments in the BBA now require nursing homes, rather than their suppliers, to bill Medicare.

HCFA Has the Opportunity to Develop New Strategies for Setting DME Fees

Until enactment of the BBA, HCFA used an "inherent reasonableness" review process, illustrated in appendix II, that was lengthy and cumbersome to adjust Medicare fees for medical equipment and supplies.[11] HCFA successfully used this process in only one case—it took HCFA almost 3 years to adjust the Medicare fee schedule allowance for blood glucose monitors. The BBA provides HCFA the opportunity to develop new strategies for setting DME fees; other approaches that also merit consideration may require additional statutory authority.

Section 4316 of the BBA allows HCFA to use a more flexible, streamlined process to adjust Medicare fees by as much as 15 percent in one year.[12] HCFA plans to implement this authority by having its contractors (1) consider relevant pricing information, such as prices listed in supplier catalogs and prices paid by the Department of Veterans Affairs (VA), and other factors in proposing changes to the fee schedule allowances;

[11]42 U.S.C. 1395m(a)(10) and 1395(u)(b)(8) and (9) (1994).

[12]42 U.S.C.A. 1395m(a)(10) and 1395u(b)(8) and (9) (West Supp. 1997).

(2) notify suppliers and state Medicaid agencies of the factors used to establish the proposed fees and solicit comments; and (3) adjust the fee allowances after considering the comments.[13] On January 17, 1998, HCFA published an interim final rule with comment period to implement these plans.

HCFA and its contractors have to overcome some problems to effectively implement these plans—the same problems encountered when HCFA asked a contractor to review the reasonableness of Medicare fees for products billed under 100 HCPCS codes. According to HCFA staff, its contractor (1) could not readily identify the specific products billed under each HCPCS code and (2) encountered problems obtaining information on market prices. Requiring UPNs on Medicare claims, as previously discussed, would help solve the first problem. To address the second problem—obtaining information on competitive marketplace prices—the contractors could use commercial pricing databases and prices set through Department of Defense competitive contracts to supplement prices obtained from catalogs and VA competitive contracts. HCFA should then require the contractors to routinely review and adjust fee schedule allowances for those HCPCS codes that account for the largest proportion of Medicare spending for DME.

On June 18, 1997, HCFA proposed a regulation that offers another strategy for paying more appropriate prices for DME. In part, the proposal would, by defining actual charges, set Medicare part B reimbursements at the lower of the fee schedule allowance or the lowest amount a provider has agreed to accept from other payers. This proposal essentially states that Medicare, as the largest single health care payer, should pay no more than the lowest amount a provider charges other payers. We believe that implementing this proposal for medical equipment and supplies could allow Medicare to pay large suppliers at rates that reflect the discounts they obtain, since those suppliers are also likely to have competitive contracts with hospital chains, nursing homes, and managed care organizations. However, a HCFA official stated that many suppliers oppose HCFA's efforts and that they would challenge HCFA's statutory authority to implement such a regulation. HCFA is reconsidering this proposal.

Subsection 4432(b) of the BBA amended Medicare law to require, in effect, nursing facilities, rather than DME suppliers and other nonphysician providers, to bill Medicare directly for DME and nonphysician services

[13]To adjust fees by more than 15 percent in one year, HCFA must still follow a complex process like that illustrated in app. II.

provided to their patients under Medicare part B.[14] This requirement will enable HCFA to identify DME supplied to Medicare beneficiaries in nursing facilities. Institutional suppliers such as those servicing nursing homes obtain DME at substantial discounts; establishing a separate fee schedule for DME provided to nursing home patients would allow Medicare to pay fees that reflect the institutional discounts, rather than paying retail prices. Pursuing this strategy could require new statutory authority for HCFA.

The use of competitive contracting for high-volume medical equipment and supplies also has merit. Section 4319 of the BBA directs the Secretary of HHS to undertake up to five competitive acquisition demonstration projects, in three competitive acquisition areas, and to complete these projects by the end of 2002.[15] Under this arrangement, medical equipment and supplies billed to Medicare part B would be reimbursed at rates set through competition. HCFA has completed the plans to administer this project but has not finalized the demonstration sites.

Conclusions

Medicare spends billions of dollars on medical equipment, supplies, and prosthetic and orthotic devices, but the prices Medicare pays reflect historical charges and, in some cases, outdated products. Similar to previous studies, our work indicates that Medicare grossly overpays for some products. Although the BBA gives HCFA greater flexibility to more quickly adjust Medicare fee schedule allowances, some underlying problems need to be resolved for HCFA to most effectively use its new authority.

Medicare overpays some claims for DME because it does not know specifically what it is paying for. Resolving this problem is fundamental to making sure that Medicare fees are reasonable. Although UPNs offer a solution to the problem, HCFA and HHS are reluctant to require UPNs on Medicare claims.

The current HCPCS codes and the fee schedule allowances do not reflect changes in products and prices brought about by improved technology and a more competitive marketplace. Some products that were once custom-made are now available as lower-cost, off-the-shelf items, but in

[14]This change will affect patients residing in a skilled nursing facility or a nursing home that includes a skilled nursing facility. Some of the benefits of consolidated billing by nursing facilities are discussed in Fraud and Abuse: Providers Target Medicare Patients in Nursing Facilities (GAO/HEHS-96-18, Jan. 24, 1996).

[15]42 U.S.C.A. 1395w-3 (West Supp. 1997).

some cases the Medicare fee schedule lists only the more expensive, custom-fabricated product.

Finally, Medicare pays institutional suppliers and retailers the same fee schedule allowances, even though large suppliers benefit from lower product acquisition costs. Medicare does not currently have a mechanism to set separate fees for large institutional suppliers and retailers so both types of providers could be fairly reimbursed for their costs.

Matters for Congressional Consideration

In order to help ensure that Medicare fees for DME are reasonable, the Congress may wish to consider enacting legislation directing the Secretary of HHS to

- reimburse providers of medical equipment, supplies, and devices at the lower of the Medicare fee schedule allowance or the lowest payment suppliers agreed to accept from other payers; and
- establish a separate fee schedule to reimburse nursing homes for the medical equipment, supplies, and devices provided to their patients.

Recommendations to the Administrator of HCFA

In order for HCFA to gather information needed to adjust Medicare fees for DME, we recommend that the Administrator of HCFA

- require suppliers to identify the specific medical equipment, supplies, and devices they bill to Medicare by including UPNs on their Medicare claims; and
- ensure that HCFA's contractors systematically gather and analyze market prices for medical equipment, supplies, and off-the-shelf orthotic devices billed to Medicare by using commercial pricing databases and considering competitive prices paid by VA, the Department of Defense, and other large payers.

We also recommend that the Administrator of HCFA

- use the authority provided by the BBA to adjust Medicare fee schedule allowances, setting a priority on items that account for the highest Medicare expenditures.

Agency Comments and Our Evaluation

We gave HHS and HCFA an opportunity to comment on a draft of this report. HHS did not provide us comments in the time required. HCFA provided us written comments, which we have included as appendix III.

HCFA agreed that Medicare overpays for some DME and stated that the revised inherent reasonableness review authority and the competitive bidding demonstration authority provided by the BBA give HCFA the tools needed to begin to address long-standing payment issues. HCFA noted that it published an interim final rule on use of its inherent reasonableness authority, is currently identifying the first items for which it will use this authority, and will announce the first site for the competitive bidding demonstration project this spring. However, HCFA raised concerns about statements in the report regarding (1) the current HCPCS billing codes, (2) Medicare fees for prefabricated orthotics, (3) the potential use of UPNs, and (4) the information available to set DME fee schedule allowances.

Current HCPCS Billing Codes

Our report states that HCFA does not know specifically what products Medicare is paying for because the same HCPCS code can be used for a broad range of product types, quality, and market prices. HCFA commented that this statement may be misleading because the HCPCS codes represent unique product categories. We disagree that our statement may be misleading. Our report notes that over 200 different catheters can be billed under HCPCS code A4338 (indwelling Foley latex catheter) and that the prices for these catheters range from about $1 to about $18 each. HCFA acknowledged that a wide variety of catheters fit this description and said that this problem could be addressed by an expansion of the single code into multiple codes if medical evidence indicates that the catheters are not functionally equivalent. However, HCFA cannot routinely perform the analysis needed to determine whether the single HCPCS code should be split into multiple codes with different fee schedule allowances. More specific product identifiers are needed to determine (1) the variety of catheters billed under the HCPCS code, (2) the quantity of each kind of catheter billed to Medicare, and (3) the marketplace prices of each kind of catheter.

Medicare Fees for Prefabricated Orthotics

Our report and a 1997 HHS OIG report noted that even though orthotic devices are increasingly available off the shelf, the HCPCS codes still reflect more costly, custom-fabricated devices. As an example, our report states that a prefabricated, self-adjusting hand/wrist brace can be purchased from a supplier's catalog for $120, but the only similar item listed in the

current Medicare fee schedule is a custom-fabricated brace with a fee schedule allowance of up to $290.92. HCFA commented that HCPCS codes L3800 and L3805 can be used for off-the-shelf hand/wrist braces and that the price comparison is flawed because the $120 price is a wholesale not a retail price. HCFA also noted that its Statistical Analysis Durable Medical Equipment Regional Carrier oversees suppliers' use of the HCPCS codes to ensure that the correct codes are used. We consulted with HCFA's statistical analysis carrier about this example during our review, and the HCPCS coordinator told us that codes L3800 and L3805 should be used for custom-fabricated hand/wrist braces. We could not reconcile the conflicting statements by HCFA and its contractor regarding which codes should be used for the prefabricated braces, and this conflicting information further illustrates our point that HCFA does not know specifically what products are being billed under the HCPCS codes. Also, if HCFA rather than its contractor is correct (that is, that HCPCS code L3805 can be used to bill Medicare for a prefabricated, self-adjusting hand/wrist brace), Medicare could be paying over a 140-percent markup over the catalog price—an amount we believe warrants review.

Potential Use of UPNs

HCFA stated that it recognizes UPNs may be useful to improve the Medicare payment system; is considering the use of UPNs; and will be looking closely at California's efforts to use UPNs in its Medicaid claims processing system. However, HCFA did not specify any project or timetable for its own efforts to evaluate the use of UPNs. As discussed below, HCFA also raised several logistical and implementation issues.

HCFA identified the need to establish a database to link functionally equivalent UPNs with HCPCS codes. To make these linkages, HCFA said that it would need to collect detailed product information for about 1.7 million products, such as the product features, the purpose and uses of the product, the number of items per package, and the manufacturer's price. HCFA also commented that it does not have the authority to require manufacturers to reveal this information and that implementing UPNs would require additional financial and personnel resources.

While implementing UPNs may require additional HCFA resources, it should be noted that HCFA and its contractors are already responsible for many of the activities HCFA described. For example, HCFA's contractors have to gather detailed information on product characteristics and prices to (1) classify products into functionally equivalent groups, (2) advise suppliers which HCPCS codes to use when billing Medicare, and (3) set an

appropriate Medicare fee schedule allowance for items billed under the HCPCS codes. Without any change in HCFA's authority, it can continue to gather information on product characteristics and prices and one additional data element—the UPN associated with the product. Similarly, suppliers can continue to bill Medicare using existing HCPCS codes as they have in the past, but also supplying one additional data element on the claim—the UPN. Then, using the claims data with the UPNs, HCFA can build a database that identifies the specific products being billed under each HCPCS code and use this database to analyze the appropriateness of the HCPCS product groupings and the Medicare fee associated with each HCPCS code.

Our report also noted that requiring UPNs on claims could help identify claims billed under inappropriate HCPCS billing codes. Such claims could be identified by using the database described to establish computerized claims processing screens of valid HCPCS/UPN combinations. In contrast, suppliers currently can claim that a low-cost product "fits" a broad HCPCS description for a higher-cost product; since the claim does not specifically identify the product, the claim may never be questioned. Contrary to one of HCFA's comments, we did not suggest that UPNs could prevent outright falsification of the information required on DME claims.

HCFA also expressed concerns that manufacturers have wide discretion in how they assign UPNs to their products; that there are no mandatory standards for UPNs; and, therefore, UPNs have no uniform meaning. We disagree that manufacturers have wide discretion in how they assign UPNs to their products. The coding councils for each of the two UPN standards strictly define how the UPN is used to represent the manufacturer, the product, and the packaging level. The two UPN standards can be used interchangeably in claims processing systems, since a portion of the UPN identifies which of the two UPN standards is being used.

Information Available to Set DME Fee Schedule Allowances

Our report recommends that HCFA ensure that its contractors systematically gather and analyze market prices for medical equipment, supplies, and off-the-shelf orthotic devices billed to Medicare by using commercial databases and considering competitive prices paid by VA, the Department of Defense, and other large payers. HCFA commented that it has explored and will continue to explore prices paid by other payers, such as VA, but that comparisons among market prices, commercial pricing databases, other competitive prices, and Medicare fees are difficult because (1) HCFA holds a unique position in the marketplace as a payer rather than a purchaser and (2) DME suppliers who deal directly with

Medicare beneficiaries, especially those in the home, have a different cost structure than suppliers to hospitals or VA.

Our report does discuss the fact that suppliers servicing Medicare patients incur administrative costs associated with documenting medical necessity and filing claims—costs they might not incur in doing business with purchasers rather than insurers. As noted in the report, we agree that these additional costs should be taken into consideration when setting Medicare fees.

Our report also notes that institutional suppliers, such as those that provide DME to patients in nursing homes, obtain substantial discounts, but those discounts are not reflected in the Medicare payments because Medicare pays the same fees to large institutional suppliers that it pays to other suppliers. Our report identifies some options for setting lower Medicare fees for institutional providers.

As arranged with your office, unless you publicly release its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will make copies available to other congressional committees and Members of Congress with an interest in these matters, and to the Secretary of Health and Human Services and the Administrator of HCFA. We will also make copies available to others on request.

This report was prepared by William Reis, Teruni Rosengren, Suzanne Rubins, and Thomas Taydus, under the direction of William J. Scanlon, Director, Health Financing and Systems Issues. Please call me at (202) 512-6806 or Mr. Scanlon at (202) 512-7114 if you or your staff have any questions.

Richard L. Hembra
Assistant Comptroller General

Contents

Abbreviations

BBA	Balanced Budget Act of 1997
DME	durable medical equipment
DMERC	durable medical equipment regional carrier
HCFA	Health Care Financing Administration
HCPCS	Health Care Financing Administration Common Procedure Coding System
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
OIG	Office of the Inspector General
UPN	universal product number
VA	Department of Veterans Affairs

Scope and Methodology

To determine how Medicare part B pays for medical equipment, supplies and orthotics—products referred to as durable medical equipment (DME)—we reviewed the federal statutes governing the fee schedules and the inherent reasonableness process for adjusting Medicare fees. We also reviewed the Balanced Budget Act of 1997 (BBA) to determine how provisions of that legislation change the process for adjusting Medicare part B fees for DME. We met with officials from the Health Care Financing Administration (HCFA) and representatives from HCFA's statistical analysis contractor to discuss how they apply Medicare's payment rules to set and adjust fee schedule allowances for the items in our study. In discussions with HCFA's claims processing contractors, called durable medical equipment regional carriers, we obtained information on their practices for adjusting state base fees and for establishing Medicare fees for new Health Care Financing Administration Common Procedure Coding System (HCPCS) codes.

We analyzed Medicare fee schedule payments for some commonly purchased medical equipment and supplies. Before deciding which products to include in our study, we reviewed listings of the top 100 HCPCS codes by total allowed charges and by total units allowed by Medicare for the first quarter of fiscal year 1996. We discussed many of these products with HCFA contractors and then selected the following for our review:

- blood glucose test or reagent strips for home blood glucose monitor, per 50 strips (A4253);
- lancets, per box (A4259);
- irrigation tray with bulb or piston syringe, any purpose (A4320);
- indwelling catheter, Foley type, two-way latex with coating—Teflon, silicone, silicone elastomer, or hydrophilic, etc. (A4338);
- indwelling catheter, Foley, two-way, all silicone (A4344) ;
- intermittent urinary catheter, straight tip (A4351);
- bedside drainage bag, day or night, with or without anti-reflex device, with or without tube (A4357);
- stoma cap (A5055);
- pouch, drainable with barrier attached—one piece (A5061);
- pouch, drainable for use on barrier with flange—two-piece system (A5063);
- skin barrier with flange—solid, flexible, or accordion, any size (A5123);
- cane, quad or three-prong, includes canes of all materials, adjustable or fixed, with tips (E0105);
- walker, folding (pickup), adjustable or fixed height (E0135);
- rigid walker, wheeled, with seat (E0142);

- commode chair, stationary, with fixed arms (E0163);
- vacuum erection system (K0163);
- tracheostomy care kit for established tracheostomy (K0165); and
- intermittent catheter with tray (code A4353).

We also reviewed Medicare payments for selected off-the-shelf orthotic devices. We reviewed the laws and regulations pertaining to the fee schedules for orthotic and prosthetic devices and discussed Medicare payment practices for orthotic devices with an official from HCFA, HCFA's statistical analysis contractor, and a representative from a medical supply distributor. We also reviewed the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and GAO reports on billing practices and payment policies for orthotic devices. We selected the following orthotic devices for review:

- wrist-hand-finger orthosis, long opponens, no attachments (L3805);
- wrist-hand-finger orthosis, addition to short and long opponens, thumb abduction "C" bar (L3810); and
- wrist-hand-finger orthosis, addition to short and long opponens, adjustable metacarpophalangeal and interphalangeal flexion control (L3860).

We also reviewed the HCPCS for DME. We discussed the products grouped under the HCPCS codes with officials from HCFA and HCFA's statistical analysis and claims-processing contractors. To identify products billed under various HCPCS codes, we analyzed product lists obtained from wholesalers, suppliers, and a commercial medical products database. We also discussed with manufacturers and distributors of medical equipment and supplies and their industry groups their perspectives on the use of HCPCS codes.

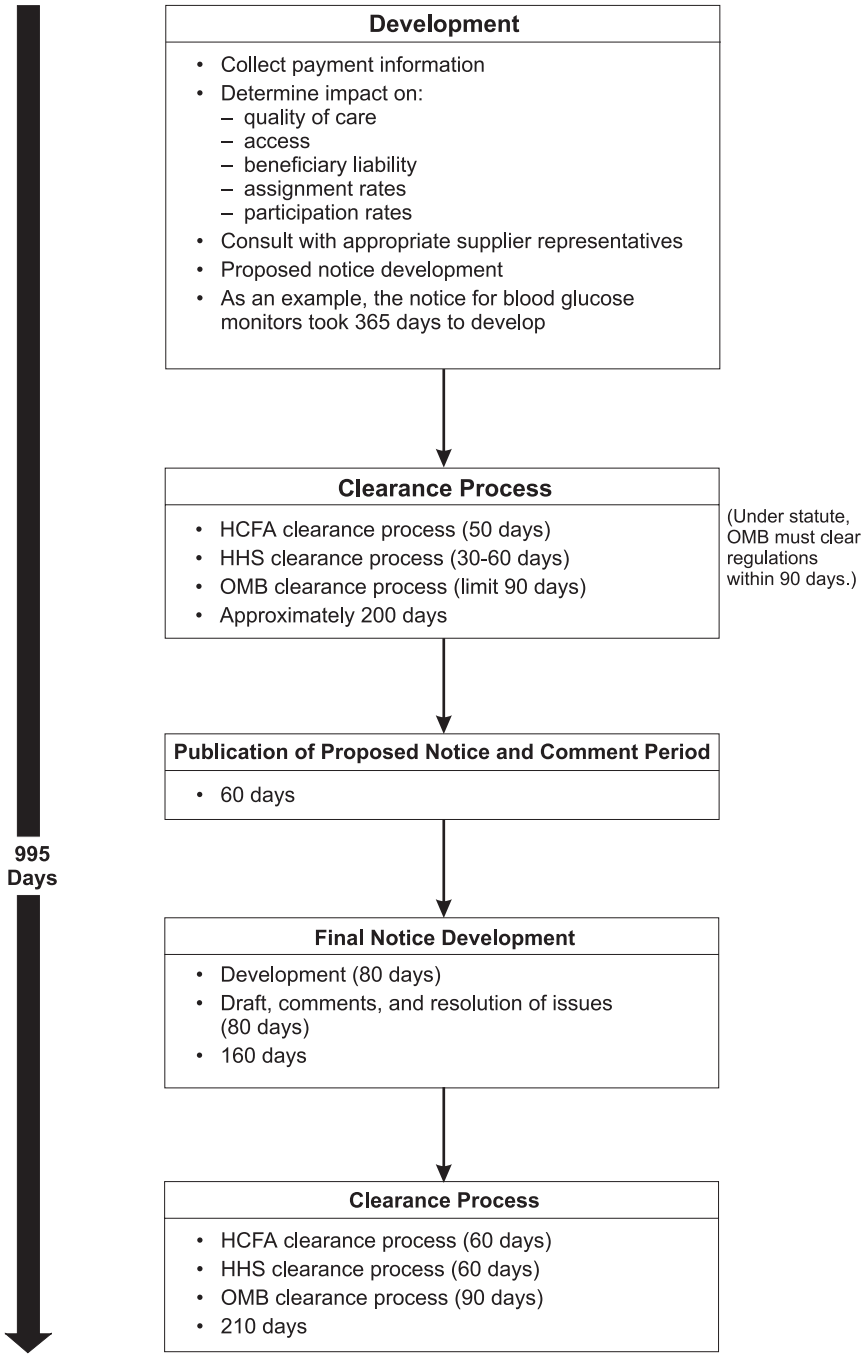
We gathered information on the use of universal product numbers (UPN) from a manufacturer, suppliers, their industry groups, hospital groups, two standards-setting organizations, the Department of Defense, and a state Medicaid agency. We met with HCFA officials to discuss the uses of UPNs and the feasibility of adopting UPNs as a national coding standard under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation.

We obtained Medicare's national floor and ceiling payment limits for selected products for the years 1995, 1996, and 1997, and we gathered comparative price information from wholesalers and manufacturers. HCFA's claims processing contractor also provided us with a comparison of

retail prices and Medicare's floor and ceiling payment rates for selected items.

We also obtained product acquisition costs for selected items from some large suppliers. To identify the suppliers, we reviewed reports from HCFA's statistical analysis contractor. The reports listed the 30 suppliers who received the highest total Medicare payments for selected products during the fourth quarter of fiscal year 1996. From some of these suppliers we were able to gather information on the specific products billed to Medicare, the suppliers' product acquisition costs, administrative costs, purchasing and distribution arrangements, and Medicare billing arrangements. Our discussions with suppliers also covered administrative costs, industry trends regarding cooperative buying groups, and other efforts to lower product acquisition costs.

Overview of Inherent Reasonableness Review Process



Comments From the Health Care Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: [redacted]

TO: William J. Scanlon
Director, Health Financing and Systems Issues
General Accounting Office

FROM: Nancy-Ann Min DeParle NMD
Administrator

SUBJECT: GAO Draft Report, "Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies"

We appreciate the opportunity to review your draft report to Congress concerning the payment for durable medical equipment and supplies. Our comments are attached. Should you have questions or require additional information, please contact Rita Reinsel of the Office of Financial Management at (410) 786-7444.

Attachment

Comments of the Health Care Financing Administration (HCFA) on the General Accounting Office (GAO) Draft Report, "Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies"

Overview

Using authority secured in the balanced Budget Act of 1997 (BBA) the Health Care Financing Administration (HCFA) is taking steps to reduce Medicare's payments for durable medical equipment (DME) and other items. HCFA agrees with the General Accounting Office (GAO) that Medicare is overpaying for some items of DME and prosthetics and orthotics. This overpayment is the result of inflexible statutorily prescribed fee schedules. In order to address the issue, the Administration for years had requested modifications to our inherent reasonableness authority, which was finally granted in the BBA. In addition, the Administration for years has requested authority to use competitive bidding to establish payment levels for Part B items based on market mechanisms. The BBA provided demonstration authority, and we are in the process of instituting a competitive bidding demonstration project for DME and other items. We believe that these new tools, provided recently in BBA, will allow us to begin to address long-standing payment issues.

HCFA also recognizes that Universal Product Numbers (UPNs) may be useful to improve the Medicare payment system. Nevertheless, we believe the GAO report overlooks key issues that must be addressed before UPNs can be used successfully as part of a claims processing system.

GAO Recommendation

We recommend that the Administrator of HCFA:

-- require suppliers to identify the specific medical equipment, supplies, and devices they bill to Medicare by including universal product numbers on their claims;

HCFA Comment

Once the proposed additional supplier standards regulations, published on January 20, 1998, are finalized, HCFA would have the authority to require suppliers to submit UPNs on their claim forms. The GAO report, however, does not make clear that this requirement is not sufficient since we would still not have the necessary information to make the UPN informative to claims processing decisions. Under current law, it is not possible to understand what each UPN represents.

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✔ Two coding councils allow the use of UPNs by assigning only a portion of the 8-20 digit UPN that identifies the manufacturer or other entity that requests to use UPNs. The entities that use these numbers then have the discretion to assign and utilize the remaining fields in the UPN for their own purposes. No mandatory standards for using UPNs currently exist, and as a result UPNs have no uniform meaning.

-- manufacturers can assign multiple UPNs to the same product for sale to different suppliers and purchasers at different prices;

-- manufacturers can assign multiple UPNs to products for which there is no distinction of their medical use, but for which there are slight manufacturing differences; and

-- manufacturers can assign a UPN to a product and change the product without changing the UPN.

✔ If HCFA required the submission of UPNs, it would not have the authority to require the manufacturers to reveal what each UPN represents. Information such as:

-- product features;
-- manufacturer's price;
-- purpose and uses of product;
-- HCPCS code with which the UPN would be associated; and
-- number of items per package

would be required in order for the UPN to provide useful information. It is possible manufacturers would consider such product information proprietary and resist any voluntary requests for information.

✔ Even if HCFA had the required information from manufacturers, such information for an estimated 1.7 million UPNs would have to be matched appropriately to a HCFA Common Procedure Coding System (HCPCS) code. The data collection, matching, and maintenance of the UPN database would require significant financial and personnel resources that are not currently in HCFA's budget, and therefore, would necessitate additional appropriations.

The GAO report highlights that many purchasers, such as hospital systems, have found UPNs useful for purchasing and inventory purposes. Such purchasers have

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to deal only with the UPNs for the items they are bidding and the manufacturers who are potential bidders. The report should have noted, however, that since HCFA has to pay for any item that might be medically necessary, the array of UPNs is expanded to the universe of all possible UPNs. In addition, while a hospital is concerned only with determining the best price for comparable products based on bid, HCFA would have to determine the appropriate Medicare payment amount or appropriate HCPCS code for each of the 1.7 million UPNs. As the report indicates, California is currently attempting to implement a UPN coding system for its Medi-Cal system. We will be following their experience closely.

GAO Recommendation

-- ensure that HCFA's contractors systematically gather and analyze market prices for medical equipment, supplies, and off-the-shelf orthotic devices billed to Medicare by using commercial databases and considering competitive prices paid by the VA, the Department of Defense, and other large payers; and

HCFA Comment

HCFA has explored, and will continue to explore, the use of commercial databases and prices paid by other payers, such as the Veterans Administration (VA). However, comparisons between market prices, commercial pricing databases, or other competitive prices and what Medicare pays are difficult because of the unique position that HCFA holds in the market place as a payer, rather than purchaser. Secondly, DME suppliers have a unique cost structure.

✔ HCFA has explored using commercial pricing databases. However, only limited comparisons can be made when the system is designed for purchasers such as hospitals that maintain inventories of items that they purchase, rather than payers such as HCFA that pay for items furnished by tens of thousands of different suppliers to individual Medicare beneficiaries.

-- HCFA has contacted one of the commercial pricing database companies and requested information on items for several of its HCPCS codes. Information on only one code was available in the system. A database designed to compare prices of hospital items may not be a useful tool for many Medicare covered items, which are used primarily in the home.

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- ✔ Local DME suppliers with whom the beneficiaries deal have a different cost structure than the supplier or manufacturer who provides items in large volumes directly to hospitals or the Veterans Administration (VA).
  - -- HCFA must consider a DME supplier's administrative costs for building space, inventory, a different billing system, costs for educating beneficiaries, delivery of items to the beneficiaries' homes, and for fitting items to beneficiaries properly.
- ✔ Notwithstanding the limitations of these databases, HCFA has and will continue to consult with the VA regarding price information to be used with appropriate adjustments in exercising our inherent reasonableness authority.

GAO Recommendation

- -- use the authority provided by the BBA to adjust Medicare fee schedule allowances, setting a priority on items that account for the highest Medicare expenditures.

HCFA Comment

- ✔ We have already published an interim final rule with a 60-day comment period implementing HCFA's inherent reasonableness authority on January 7, 1998.
- ✔ We are currently determining the items for which we should first use our inherent reasonableness authority.
- ✔ We will be announcing the first site for the competitive bidding demonstration project this spring.

Specific Comments:

Now on p. 3.

1. The report on page 4 states that HCFA does not have any plans to require UPNs on Medicare claims. This statement fails to acknowledge that we are considering the use of UPNs but must consider the potential logistical and cost issues involved. It would have been helpful if the report had considered these.

Now on p. 2.

2. The report on page 4 states that the HCFA billing codes cover a broad range of product types. This statement may be misleading. There are approximately 2,400 HCPCS codes. Each code represents a particular type of product, e.g., EO652 is defined

as "pneumatic compressor, sequential home model with calibrated gradient pressure." These codes represent unique product categories rather than a broad range of product types.

Now on p. 3.

3. The report on page 5 states that there is no HCPCS code for prefabricated, self-adjusting hand/wrist braces. This statement is not correct. Codes L3800 and L3805 can be used for prefabricated, self-adjusting hand/wrist braces. The report also mentions a supplier's catalog price of $120.00. It is our understanding that this price is a wholesale, not a retail price. Therefore, the comparison to the Medicare fee schedule amount is flawed. At a minimum, the report should have addressed what would be an appropriate mark-up in the case of a wholesale price.

Now on pp. 3 and 4.

4. The report on page 6 states that when suppliers bill Medicare, they use the HCPCS code they believe best describes the specific product provided to the patient. However, the report fails to explain the role of the Statistical Analysis Durable Medical Equipment Regional Carrier in overseeing this process to ensure that the correct codes are used.

Now on p. 5.

5. The report on page 8 states that HCFA does not know specifically for what it is paying when it processes claims. This statement may create a false impression. For example, in discussing catheters, when we pay for code A4338, we do know that we are paying for an indwelling catheter, foley type, 2-way latex with coating. As the report indicates, there are a wide variety of catheters that fit this description. This problem could be addressed, however, by an expansion of the code into multiple codes if medical evidence indicates that the catheters are not functionally equivalent.

Now on p. 5.

6. The report on page 8 states that GAO investigators identified the products billed under some HCPCS codes and found that the Medicare payment was appropriate for a few of the products, but was grossly excessive for many billed under the same code. The report should also indicate that for some products the industry would claim that our payment amount is grossly deficient.

Now on p. 5.

7. The report on page 8 states that products that differ widely in properties, use and performance, and price are being billed under the same HCPCS code. The example given in the report is code A4338. This code is described as an indwelling catheter, foley type, two-way latex, with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.). We believe that it is misleading to state that indwelling catheters, foley type, two-way latex, with coating differ widely in properties, use and performance. They are all used to drain the bladder. They are all indwelling as opposed to intermittent catheters. We are not aware of any clinical studies that demonstrate the advantages of teflon versus silicone, silicone elastomer, or hydrophilic coated catheters.

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Also, while manufacturers may claim that their particular coating causes fewer patient reactions, this report suggests that most patients are receiving the least expensive variety. This may mean that most patients do not require a special coated catheter. We also ask that the report indicate how it distinguishes between short-term, medium-term, and long-term catheters. We are particularly interested in what would prevent any and every manufacturer from considering its product to be for long-term use.

Now on p. 5.

8. The report on page 9 suggests that some suppliers are purposely billing the wrong code to obtain a higher payment amount. UPNs would not eliminate this problem since suppliers could purposely bill the wrong UPN.

Now on p. 6.

9. The report on page 10 states that the alpha-numeric UPN provides very detailed product information. We question the correctness of this statement. The report should explain, how the UPN provides such detailed information, especially in terms of how the UPN can be used to determine which products are functionally equivalent.

Now on p. 9.

10. The report on page 15 states that the administrative costs of suppliers do not account for the disparity between large suppliers' unit costs and Medicare payment amounts. The report then states that administrative costs are largely attributable to documenting the medical necessity of the claim which is about $10.00. How should other costs associated with running a business (such as overhead, delivery, maintaining inventories, and patient education) be considered in determining Medicare payment?

Related GAO Products

Medicare: Home Oxygen Program Warrants Continued HCFA Attention (GAO/HEHS-98-17, Nov. 7, 1997).

Medicare: Problems Affecting HCFA's Ability to Set Appropriate Reimbursement Rates for Medical Equipment and Supplies (GAO/HEHS-97-157R, June 17, 1997).

Medicare: Comparison of Medicare and VA Payment Rates for Home Oxygen (GAO/HEHS-97-120R, May 15, 1997).

Nursing Homes: Too Early to Assess New Efforts to Control Fraud and Abuse (GAO/T-HEHS-97-114, Apr. 16, 1997).

Medicare Post-Acute Care: Home Health and Skilled Nursing Facility Cost Growth and Proposals for Prospective Payment (GAO/T-HEHS-97-90, Mar. 4, 1997).

Fraud and Abuse: Providers Target Medicare Patients in Nursing Facilities (GAO/HEHS-96-18, Jan. 24, 1996).

Medicare Spending: Modern Management Strategies Needed to Curb Billions in Unnecessary Payments (GAO/HEHS-95-210, Sept. 19, 1995).

Durable Medical Equipment: Regional Carriers' Coverage Criteria Are Consistent With Medicare Law (GAO/HEHS-95-185, Sept. 19, 1995).

Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements (GAO/HEHS-95-171, Aug. 8, 1995).

Medicare: Adapting Private Sector Techniques Could Curb Losses to Fraud and Abuse (GAO/T-HEHS-95-211, July 25, 1995).

Medicare: Separate Payment for Fitting Braces and Artificial Limbs Is Not Needed (GAO/HRD-93-98, July 21, 1993).

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