CMS Bidding System Will Increase Medical Costs:

A Cost/Benefit Analysis

Steve Pociask President American Consumer Institute Center for Citizen Research

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American Consumer Institute Center for Citizen Research 1701 Pennsylvania Ave., NW Suite 300 Washington, DC 20006

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Introduction and Executive Summary

The Centers for Medicare & Medicaid Services (CMS) is implementing a bidding program that it hopes will lead to lower-priced devices and drive down Medicare costs for the homecare patients. However, auction bidding experts have overwhelmingly found that the current program will lead to below-cost pricing, which would adversely affect supply. The resulting decrease in the supply of medical devices for homecare patients, as this study shows, would create significant increases in other medical costs for some Americans.

As an example of this problem, this paper analyzes a high-tech solution for wound treatment – Negative Pressure Wound Therapy (NPWT) – and finds its upfront cost to be indeed higher than traditional care. However, this analysis shows that NPWT devices produce about seven times more benefits than costs to society and superior patient outcomes compared to standard care. Therefore, if the CMS bidding process reduces supply and homecare patient access to NPWT devices, total medical costs will increase as patients experience longer stays in hospitals, and will see increased risks of reinfections and complications, such as increased amputation, ambulatory care and prosthetics.

Ironically, an auction bidding program that seeks to minimize Medicare costs could lead to significantly higher medical costs to society as a whole, as well as worse outcomes for Medicare patients. Thus, the objective of minimizing CMS budget dollars could raise the cost of medical care in the U.S., particularly for non-commodity devices, such as innovative and complex medical equipment.

Inefficient Procurement Auctions

The CMS is currently implementing an auction bidding program for medical devices that it hopes will reduce government medical costs. However, an analysis by Professor Cramton,² as well as a letter to members of U.S. Congress written by 167 economists and auction experts,³

¹ Steve Pociask is president of the American Consumer Institute, Center for Citizen Research, a nonprofit 501c3 educational and research institute. For more information, visit <u>www.theamericanconsumer.org</u>.

² Peter Cramton, "Auction Design for Medicare Durable Medical Equipment," Nov. 23, 2010. See also Jan Ayres and Peter Cramton, "Fix Medicare's Bizarre Auction Program," *New York Times*, Sept. 30, 2010.

³ Letter to Honorable Pete Stark (Chairman of the U.S. House of Representatives Subcommittee on Health, Committee on Ways and Means) from 167 economists and auction experts, September 26, 2010.

concluded that the medical device bidding program that is being implemented by the CMS is faulty and would set Medicare prices below market equilibrium (below cost). Agreeing with that assessment, professors Fuhr and Blackstone found that the new bidding program would not only result in prices divergent from efficient market competition, but would also lead to a reduction in product quality and service, as well as fewer medical suppliers and supply shortages.⁴ Fuhr and Blackstone also conclude that the new bidding process would undermine incentives for medical device innovation. They conclude:

This will lead to lower quality of life for the elderly through longer hospital stays, more emergency room visits, and loss of independence if the elderly can no longer stay at home and must go into long term care. An added consequence is higher cost of care as more beneficiaries are shifted from low cost home health care to higher cost facilities. The auction system as presently comprised will lead to government failure and decrease consumer welfare.

Experimental auctions conducted by professors at California Institute of Technology compared the proposed CMS approach with well-accepted auction methods found that the proposal produced below cost bids:

We conclude that (1) good auction architectures do exist; (2) the CMS auction is not a good procurement auction because it is based on an inappropriate architecture that cannot deliver services at competitive rates and qualities; and (3) the CMS auction cannot be adjusted in some simple way – there is no "quick fix." The two central pillars are intrinsically flawed. Price determination by the median accepted bid is not an appropriate method for determining price and the ability of bidders to withdraw bids is an inappropriate guide for competitive bidding strategies.⁵

Since, according to current CMS rules, the lowest bidder is permitted to sell at a higher auction price (the median price). This creates incentives to bid below market price in order to win the right to supply. Because auction bids are nonbinding under the CMS approach, low-bid winners are not required to supply devices. This means that winners who "low-ball bid" can refuse to supply any device at the final auction price, which will drive down prices, create shortages and lead to fewer suppliers. This conclusion is completely consistent with well-

⁴ Erwin A. Blackstone and Joseph P. Fuhr, "Bidding Farewell: How the Medicare Auctions Could Severely Reduce Durable Medical Equipment Supplies and Harm Homebound Elderly Patients, The American Consumer Institute Center for Citizen Research, Washington, DC, March 21, 2011.

⁵ Brian Merlob, Kathryn Peters, Charles R. Plott, Andre Pradhana and Yuanjun Zhang, "An Evaluation of the Proposed Procurement Auction for the Purchase of Medicare Equipment: Experimental Tests of the Auction Architecture," Working Paper, California Institute of Technology, November 2010. While in practice and in test simulations, competitive bidding that are binding and go the lowest bidders do work, are efficient and produce stable equilibriums. On the other hand, the CMS bidding process has been shown to be inefficient and yield low-ball prices, according to bidding simulation at Cal Tech. Since the CMS process does not require winning bids to be binding, shortages are highly likely. The authors found that requiring a small fee for the right to bid somewhat increased efficiency, but greatly reduced the number of suppliers.

accepted microeconomic theory – namely, setting price below cost always produces shortages and causes firms to exit the market.⁶ This means that demand for medical devices to homecare patients will not be fulfilled and consumer welfare will decline. Limiting the availability of these devices to homecare patients also means that medical outcomes could be compromised, leading to higher hospital costs and Serious Harm. These and other concerns have led to the introduction of legislation to postpone Medicare bidding process. This report will use a cost/benefit approach to provide evidence on the impact that the current bidding process will have on medical patients and society.

Anecdotal Evidence

CMS has begun a limited implementation of its bidding program. However, the resulting news reports and other sources cite examples that are consistent with economists' and auction experts' predictions regarding the consequences from the implementing the new CMS bidding program. For instance, one article reported 250 complaints resulting from the new bidding system and an increase in patients being admitted to the hospital for services that were "once standard at-home procedures."⁷ Another report suggested adverse consequences on rural medical suppliers.⁸ One elderly patient needed to stay in the hospital for four extra days, because her doctor was unable to find her oxygen supplies for home use.⁹ The American Association for Home Care has also reported a number of problems and in several cities, including medical device shortages and suppliers going out of business.¹⁰ Policy analysts are expressing similar concerns.¹¹ It is expected that a wider implementation of the program will result in reduced prices that will limit the extent of the market and reduce supplies to homecare patients. Once this has occurred and suppliers have left the market, it will not be easy to fix the damage inflicted upon patients, suppliers and market structure.

Effects on Innovation

Another potential problem is that the current bidding process tends to undermine product innovation. Since the bidding process locks in durable medical products for three years, a newly approved FDA product may need to wait years to be included for bidding. The added wait time means reduced demand and reduced return on investment, which discourages research and development for innovative durable medical devices.

Correctly done, competitive auctions can be quite efficient in determining market prices, at least for commodity goods or goods that are homogeneous in nature. However, bidding on somewhat differentiated products within the same category may lead to suboptimal results, unless more information is first known. For example, if a high-tech and somewhat

⁶ Shortages result from setting artificially-low prices, and the effect is identical to price controls in competitive industries. See C. E Ferguson and J. P. Gould, *Microeconomic Theory*, Richard D. Irwin, Inc. Homewood Illinois, 1975, pp. 302-304. Ferguson and Gould note that the effect of pricing below equilibrium levels will mean that "ultimately all firms will leave the industry," at p. 303.

⁷ Kevin McGuire, "Implementation of Bidding System Failing Seniors, HULIQ.com, Feb. 25, 2011.

⁸ "Medicare Wheelchair Policy Will Hurt Access to Care in Rural Areas," *Disabled World*, Dec. 4, 2010.

⁹ David Kopf, "Charlotte Patients Can't Get HME," *HME Business*, January 20, 2011.

¹⁰ See <u>http://blog.aahomecare.org/</u>.

¹¹ For example see the Heartland Institute's clearing house on this issue at <u>http://medicaldevicefreedom.org/</u>.

more expensive durable medical device is lumped together for bidding with a lower-quality medical device, even under a perfectly designed competitive bidding process, the lower quality medical device will always win the competitive bid over the more expensive and innovative product. This is the nature of placing products with different functions, features and durability into the same product category, and expecting the same outcomes. Unless the CMS explicitly knows that similarly categorized products will achieve exactly the same medical outcomes, it is possible that the program will decrease the demand for some innovative products and that will lead to inferior outcomes for patients, thereby reducing the quality of care and undermining investments in these innovative products. Moreover, if a more expensive product yields shorter hospital stays, as well as a reduction in complications, infections and hospital readmittance, that product can save society thousands of dollars per patient, but may lose the auction bid by a matter of cents. Thus, innovative and complex products could appear more costly over standard care or over lower-quality devices, unless they are evaluated based on a strict cost/benefit test. In this case, using a competitive auction will not necessarily produce the best choice for society, as it would for homogeneous commodities. Therefore, for noncommodity devices and complex high-tech devices, the CMS bidding process could have a bias against quality and innovation.

Besides the problem of low-ball bidding induced by the faults in the CMS auction methodology, some higher technology devices require training, national infrastructure for support and, most importantly, physician trust in order to move patients with these devices safely and effectively from the hospital care to the homecare setting. If, for example, physicians are unfamiliar or less confident with off-brands or lower-quality devices made available through auctions for homecare use, these devices are less likely to be prescribed for patients. In addition, doctors may want some confidence in knowing that complex homecare devices have expertly trained and knowledgeable paraprofessionals available to service, support and maintain these varied home products. Without trust, physicians could shy away from using complex and less common homecare solutions, instead opting for less effective traditional care or longer hospital stays. Thus, patient outcome could be compromised and medical complications could result in hospital re-admittance and/or increased medical costs for Medicare patients.

These examples are not just a hypothetical, as the next section will show.

The Case of Wound Care Devices

Negative Pressure Wound Therapy (NPWT)¹² is a medical device used to promote the healing of large wounds by providing a moist and closed environment. The device has been shown to reduce the presence of edema and infectious material in wounds; promote tissue granulation, formation, and perfusion; and bring the edges of wounds closer together. Because the device requires training and is high-tech in nature, its use is significantly more expensive than traditional wound care, which may consist of wound dressings, such as saline gauze. Although

¹² In this study, the term *Negative Pressure Wound Therapy* is sometimes used interchangeably with the term *Vacuum-Assisted Closure* (VAC) care, a product in widespread use today.

it is much more costly to use than bandages, there are many empirical studies (see the list of medical studies at the end of this paper¹³) that show NPWT to produce superior outcomes versus standard care. These studies also find that NPWT is so effective in promoting healing that its use reduces hospital stays and the probability of infections, which lower total medical costs.

For example, the Weinberg Group (1999) found NPWT to heal much faster than standard care. As the table below shows, the Weinberg Group study found at standard care healed 12 of every 100 wound patients over a six-month period, compared to 68 for NPWT.¹⁴

	Healed	Progressing	Other	Total
Standard	12%	69%	19%	100%
NPWT	68%	28%	4%	100%

Table 1: Weinberg Group Results on Standard Care vs. NPWT

The Weinberg Group study also found that hospital stays were shorter with NPWT, leading to lower total costs. This finding was confirmed by numerous other studies. Kaplan (2009) found that early use of NPWT produced significant savings for trauma patients. Of 1000, patients receiving NPWT after three days, total costs were \$43,956 and required 20.6 hospital days. However, for the 518 patients receiving NPWT within three days, total costs were \$32,175 and required 10.6 days. So, while average daily costs were higher, the early use of NPWT required ten fewer hospital days and saved \$11,781 in total costs.

The savings for patients with diabetic foot wounds were also significant. Philbeck (2001) found hospital stay costs were reduced by \$4,333 for diabetic foot ulcers, while Flack (2008) found NPWT to have saved 11 hospital days or about \$21,900.¹⁵ Apelqvist (2008) found the savings to be \$12,852 for diabetic foot wounds; and Vuerstaek (2006) found hospital stay fell from 17 to 7 days for chronic leg ulcers or, by our estimate, approximately \$19,900 in savings.

However, the economic benefits of using NPWT could be much larger than simply reducing hospital days, because they could also reduce reinfections and, in particular, amputations that lead to future events and costs. Andros (2006) found the 1,000 patients that received NPWT to have produced \$11,958 in savings per patient over the 586 patients that received standard care. However, because NPWT reduced the probability of amputation, an additional \$19,958 of cost was avoided from amputation, as well as an additional \$20,000 to

 ¹³ This section will briefly review these study findings. A list of studies can be found at the end of this paper.
¹⁴ Weinberg Group, p. 12.

¹⁵ This is our estimate. Based on nearly 40 million discharges and according to U.S. Department of Health and Human resource data for 2008, the average hospital length of stay was 4.6 days and the mean costs were \$9,170, or \$1,993 per day. This average cost per day is used to convert the reduction in length of stay into direct savings. See www.hcupnet.ahrq.gov for access to these national statistics.

\$40,000 of cost avoided for ambulatory care and prosthesis. Therefore, NPWT saved between \$51,922 and \$71,922 for the 5.8% of patients who would have lost a limb.

In addition to NPWT's savings over standard care, Schere (2002) found additional savings by avoiding re-admittance. Specifically, he found that 16% (19% for standard minus 3% for NPWT) of patients would need to repeat skin grafts at a cost of \$63,791 per patient – or an average savings of \$10,200 per patient. This savings is addition to the NPWT savings from the initial skin grafts.

Savings were found for patients with abdominal compartment syndrome. Kaplan (2004) found a 26% cost reduction or, by our estimate, \$21,900 savings. Niezgoda and Menez-Eastman (2009) found reductions in hospital stay amounting to \$31,842 of savings for abdominal compartment syndrome savings and \$33,040 of savings from possibly amputation cases, by our estimate of average costs per day.

Other studies show savings as well. Philbeck (1999) found \$8,919 in savings for trochanteric and trunk wounds. Siegal (2007) found hospital stays decreased from 42 days to 3 days for patients with soft tissue sarcomas – a savings of \$77,700, by our estimate of average cost per day.

Assumptions of Savings

This section will estimate the potential U.S. savings from NPWT, based largely on the previous literature review. These savings will be multiplied by the 2010 demand for NPWT. The U.S. NPWT demand (wounds) and potential demand (medically appropriate wounds) were taken from estimates made by L.E.K interviews and analysis, including estimates for pressure ulcers, surgical, trauma, diabetic foot ulcers, venus leg ulcers and arterial ulcers.¹⁶ These data include the quantity of wounds using NPWT in various hospital and homecare settings.

Based on the studies discussed in the earlier section, it is assumed that NPWT can produce a modest "base case" savings of \$8,000 for pressure ulcers, surgical, trauma, venus leg ulcers and arterial ulcers wounds. In addition, it is assumed that 16% fewer skin graft patients will not require repeat procedures for these wounds, as noted in Schere, et al (2002). However, Schere's estimated cost of repeat procedures (\$63,791) is assumed to be lower (\$25,556), in order to keep the savings estimate reasonably conservative.¹⁷

Of trauma wounds using NPWT, 20% are assumed to abdominal wounds with the average savings identified by Kaplan (2004) and Niezgoda and Menez-Eastman (2009). For obvious reasons, it is assumed that NPTW would not be used for abdominal compartment syndrome while in homecare settings. For diabetic foot wound cases, this analysis does not use the base case assumption of \$8,000. Instead, based on the literature, a higher savings

¹⁶ "U.S. NPWT / V.A. C. Market Landscape," L.E.K., 2010.

¹⁷ This lower figure came from <u>www.hcupnet.ahrq.gov</u> and represents the mean average cost of 48,073 skin grafts. While average mean costs are estimated to be \$25,566, mean price is much higher at \$79,740.

(\$12,000) is assumed for diabetic foot wound cases, plus an additional benefit reflecting the 5.8% of patients that avoid amputation, ambulatory care and prosthetics (using the average benefit and probability provided by Andros). No additional costs were applied to pressure ulcers, venus leg or arterial ulcers.

NPWT Benefits Far Exceed Costs

The average benefit of NPWT weighted by wound type for 2010 is estimated to be \$10,700 per wound. Based on 661,100 wounds treated using NPWT in the U.S. and given the assumptions for savings, it is estimated that the annual economic benefits from NPWT would be \$7.1 billion, and the potential benefits (given the quantity of medically appropriate wounds) would be \$14.8 billion. This means that NPWT produces large benefits for patients. In addition, based on the potential benefits, these devices are being underutilized and would produce even greater economic benefits to patients, if more widely used. Furthermore, if treatment became more common in the homecare setting, hospital costs would continue to be avoided.

To put this savings into context, the total costs for NPWT therapy in the U.S. is only about \$1 billion.¹⁸ In other words, \$1 billion of NPWT costs produce more than seven times the benefit, given current demand. Simply put, the economic benefits of NPWT, measures by the average savings times the quantity, significantly exceeds its direct cost. **Chart 1** (below) summarizes this finding.



CMS Bidding Program Would Increase Some Medical Costs

CMS seeks lower Medicare costs through a bidding process. As discussed earlier, the current CMS bidding program could result in a reduced demand for NPWT devices, by low-ball bidding and by favoring price over quality. This means that physicians are likely to move

¹⁸ "Negative Pressure Wound Therapy Market is Hotly Contested," *BioPharma Today*, June 16, 2009, available at <u>http://www.biopharmatoday.com/2009/06/negative-pressure-wound-therapy-market-is-hotly-contested-.html</u>.

patients away from NPWT to more traditional forms of wound treatment, such as moist bandages, even though these treatments lead to higher medical costs. Therefore, if CMS costs are reduced by \$1, nearly \$7 of economic benefits will be lost due to longer hospital stays, increased re-admittance due to inflections, more amputations and so on.

Instead of picking the wound care treatment that produces more benefits than costs, in this case, the CMS bidding system would select the low cost and low quality solution, which ultimately increase the total medical costs to society. It may also be the case that choosing lower-end NPWT products may have suboptimal results. So it is not clear that choosing this medical device based solely on its direct cost is the right parameter for product selection. Rather, the right parameter would appear to be one that produces better outcomes for patients and one that leads to lower total medical costs. In this case, NPWT appears to do both and clinicians are in a better position to see this tradeoff then blindly through automated auctions.

Conclusion: Bidding May Not Be Appropriate for Complex Devices

This analysis suggests that, for non-commodities, the CMS bidding may favor less innovative and lower-quality devices. Furthermore, there are numerous reports from experts concluding that the CMS bidding program would produce artificially lower prices for devices, which will lead to shortages and few suppliers. This means that patients will have limited access to these devices for homecare use, which will lead physicians to move patients away from innovative devices to lower quality devices and more traditional care.

As an example, this study looked at the impact that the CMS bidding program would have on NPWT devices. If physicians prefer different NPWT devices than those available through CMS for home use, they may not elect to prescribe these home care devices. Furthermore, if patients do not have adequate access to NPWT devices, because of shortages, physicians will simply turn to traditional wound dressings or require longer hospital stays. As this analysis has shown, NPWT produces \$7 of benefits for every \$1 of costs, and it produces better outcomes for patients, compared to traditional treatments. This means that the CMS bidding program will reduce NPWT in the homecare setting, raise overall medical costs and lead to lower quality care for Medicare patients – including increased infections, increased readmittance, longer hospital stays, more amputations and longer healing times.

Increasing medical costs and producing lower quality patient outcomes should not be the goal of CMS bidding program.

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