

SUBMITTED VIA ELECTRONIC FILING

August 31, 2009

Re: CMS-1413-P: Section I.G.5. Incentives for Electronic Prescribing (E-Prescribing); Section I.H.1. Part B Drug Payment, Average Sales Price (ASP) Issues; and Section I.O. Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)-Related Issues.

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA)¹ offers the following comments to the above referenced sections of CMS' proposed Medicare Program rule regarding E-prescribing, ASP and DMEPOS issues.

I. E-PRESCRIBING CAPABILITY (Section I.G.5.)

E-prescribing is intended to foster better, quicker, safer, more efficient and less costly communications between providers and pharmacies/pharmacists regarding patient prescriptions and their conditions. NCPA was thus understandably concerned that MIPPA provided 2009 – 2013 incentives for providers to e-prescribe (and 2012 - 2014 penalties for failure to do so), yet did nothing to encourage e-prescribing on the pharmacist side of the relationship. The imbalance is of concern not only on the basis of equity and fairness, but also in light of effectively encouraging a robust system of E-prescribing.

While NCPA recognizes that CMS is largely implementing the intent and specific dictates of the e-prescribing mandates of MIPPA, NCPA has the same equity and effectiveness concerns regarding standards that providers have to meet in this proposed rule to be considered "successful e-prescribers", and thus eligible to receive incentives/avoid penalties. Specifically, we are concerned that a prescriber would only have to e-prescribe 25 times during the 2010 reporting period to be eligible for the incentive of 2% of all total estimated allowed charges covering all professional services furnished during the 2010 reporting period.²

¹ The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States.

² Eligible professional would be required to report that at least 1 prescription for a Medicare Part B FFS patient created during an encounter that is represented by 1 of the codes in the denominator of the electronic prescribing measure was generated using a qualified e-prescribing system for at least 25 times during the 2010 reporting period. (Pg. 33598). CMS extrapolates that a group practice would have to report that at least 1 prescription during an encounter was generated using a qualified e-prescribing system in at least 2,500 instances during the reporting period. (Pg. 33599).

NCPA believes that there are at least four reasons why the level of e-prescribing CMS proposes to require for providers to be eligible to receive is undesirably low:

- 1) it is not “fair” to reward providers with a generous e-prescribing bonus for conducting minimal levels of e-prescribing, while pharmacies and pharmacists receive no federal bonus for doing so;
- 2) it is an unsound use of taxpayer funds to provide such large sums of money for what might be an overall very small driving force to promote e-prescribing;
- 3) the level is so low that it might actually discourage an increase in e-prescribing by some providers, as some physicians might have been prepared to conduct much higher levels of e-prescribing, but would now be glad to be able to continue with their traditional paper and fax prescribing methods (except for in a very limited number of cases); and
- 4) the low level will likewise discourage both more participating pharmacists, and also greater participation by those pharmacists, as they will be discouraged from spending the funds and taking the time necessary to e-prescribe, when they believe – perhaps correctly – that doctors will not significantly increase their level of e-prescribing, and thus the pharmacy’s efforts will not be worthwhile.

While NCPA recognizes that the current MIPPA standard of 50% of G codes showing e-prescribing is complicated by the many qualifications, NCPA asks CMS to consider the minimum reporting threshold for e-prescribing that is being advocated by SureScripts³ in their response to CMS-1413-P, of between 250 – 500 prescriptions a year per eligible professional, and 25,000 – 50,000 per year, per group practice of at least 200 eligible professionals. At the very least, NCPA requests CMS to present compelling reasons for proposing its low standards.

II. AVERAGE SALES PRICE (ASP) ISSUES (Section I.H.1)

NCPA is very concerned with the proposal to continue the 5 percent applicable threshold percentage for both the WAMP and AMP for CY 2010, which CMS has done every year since CY 2005.⁴ NCPA objected to the original enactment of that standard because in many cases it reimburses pharmacies less than their acquisition cost and does not provide adequate reimbursement to cover administrative and overhead costs.

³ Surescripts is the result of the merger in June 2008 of SureScripts, LLC and Rx-Hub, LLC. SureScripts, LLC, which focuses on electronic routing of electronic prescriptions and refill renewal between physician offices and pharmacies, was founded in August of 2001 by the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), which together represent the interests of the 55,000 independent and chain community pharmacies throughout the United States. RxHub, LLC, which has expertise in patient identification and delivering prescription drug benefit information to the physician at the point of care, was founded in the same year by the nation’s three largest pharmacy benefit managers (PBMs): CVS Caremark Corporation, Express Scripts, Inc. and Medco Health Solutions, Inc.

⁴ Section 1847A(d)(3)(B) of the Social Security Act allows to the Secretary to adjust WAMP and AMP for CY 2006 and subsequent years.

Further, the current arrangement, as in previous years, does not increase supply or dispensing fees for Part B medications to help offset low reimbursements under ASP – which are often below acquisition costs for most independent pharmacies -- and administrative costs incurred in Medicare Part B claim submission. The end result is that many of our members have advised us that they have been forced to stop providing Part B medications which decreases access for patients. Many of these medications, particularly cancer-battling drugs, are expensive, and pharmacists incur significant losses when dispensing those medications. By way of example, an independent pharmacist dispensed a month's supply of Xeloda at an ingredient cost of \$1,291.99, yet was reimbursed only \$1,210.29 by the plan – a loss of \$81.70, not including the costs of operating the pharmacy and later the same medication was dispensed at an ingredient cost of \$1,296.30, which was reimbursed by another plan at only \$1,200.76 – \$95.54 below acquisition costs.

NCPA strongly urges that Part B drug supply and dispensing fees be increased for CY 2010 to help offset low reimbursement amounts realized under the ASP method, and administrative costs associated with Part B claims.

III. DURABLE MEDICAL EQUIPMENT-RELATED ISSUES (Section I.O.)

The primary concern for independent community pharmacies for part B payment policy for CY 2010 is the near- and long-term ability of independent pharmacies to continue to participate in the program and provide DMEPOS to their patients, in the face of the competitive acquisition program, and accreditation and surety bond requirements that CMS is scheduled to soon fully implement.

Regarding competitive bidding, in the aborted first round, less than two percent of the suppliers submitting bids were independent pharmacists, despite the fact that community pharmacies hold one-third of all, and one-half of the active, supplier numbers. CMS indicated in its January 2, 2009, final competitive bidding rule that it is inclined to proceed with a national mail order program for DMEPOS and to place retail diabetes test supplies in future rounds of the competitive bidding program.⁵ Taking either action would result in significant further departures of independent community pharmacies from the program due to the inability to sustain financial losses for the sake of continuing to provide quality health care to their patients. The loss of access to care would dramatically outweigh any initial cost savings that could appear on CBO balance sheets for CMS.

CMS' intended steering of patients to mail-order suppliers does not solve the problem of patients having multiple needs and thus now having to turn to multiple sources to address those needs, nor does that policy take into account the valuable consultation, fitting and

⁵ CMS-1561-IFC, Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) at pages 2873 - 2881 of the Federal Register, Vol. 74, No. 26, January 16, 2009, at 2878.

monitoring services that independent pharmacists provide. Various studies have documented the benefits of personal care, particularly in diabetes care, and some have extrapolated the negative effect on patient care of placing diabetes test supplies in competitive bidding. Given these studies, it is particularly unfortunate that CMS chose to omit diabetic test supplies from the categories of products evaluated during competitive bidding demonstration projects. If CMS were to place retail diabetic test supplies in the program without having studied the effect of doing so, it would be choosing an unsound policy that NCPA believes will negatively impact patient care.

The more immediate concerns are that CMS requirements provide that part B DMEPOS suppliers will not receive Part B payments from CMS for the provision of Medicare DMEPOS if the suppliers do not meet the accreditation and surety bond requirements by October 1 and October 2, respectively.

CMS has yet to formally respond to NCPA regarding our explanations of why CMS has the authority to exempt pharmacies from these requirements. It has also declined to formally address the explanations of the substantive harm to pharmacies, and thus to patient access and care, that would be caused by continuing to fully implement the requirements on pharmacies. While we have continued to communicate with CMS individually and through coalitions such as the Diabetes Access to Care Coalition, the inability of CMS to adequately address these issues has forced NCPA to pursue legislative options. Such options include both blanket exemptions for pharmacies, and also for limited exemptions, which include provisions that CMS could create accreditation requirements that are specifically tailored to pharmacies.

Because of CMS' announced intention to likely place retail diabetes test supplies in the competitive bidding in round two and beyond, and because we hope that CMS will take advantage of yet another opportunity to formally address the concerns of independent community pharmacy on these issues, NCPA closes these comments with a brief discussion of the impact of these DMEPOS programs upon independent community pharmacy.

First, NCPA attaches at the conclusion of these comments a memorandum by the law firm Bryan Cave, in which the firm concludes that CMS clearly has the authority to grant pharmacies exemptions on both the accreditation and surety bond requirements.

Second, the accreditation requirements are redundant and overly burdensome. Community pharmacists already must meet many accreditation requirements and are subject to oversight and regulation both as state-licensed medical professionals and as state-licensed businesses. These laws and regulations already carry civil and criminal sanctions for violations. In September 2008, CMS exempted seventeen other types of medical professionals from accreditation:

Physicians	Occupational Therapists	Physician Assistants
Physical Therapists	Nurse Practitioners	Clinical Nurse Specialists
Certified Nurse-Midwives	Clinical Social Workers	Registered Dietitians
Nutritional professionals	Clinical Psychologists	Prosthetists
Audiologists	Orthotists	Opticians
Qualified Speech-Language Pathologists	Certified Registered Nurse Anesthetists	

CMS offered no valid reason why state-licensed pharmacists have not received this same exemption, and instead cited the types of oversight and regulation, and training and expertise shared by pharmacists and these professionals, as reasons for exempting (only) these other professionals.

Third, CMS has not addressed how the imposition of the accreditation and surety bond requirements will improve patient care and access to that care. NCPA believes that it will damage both. Initial accreditation fees and training, education and implementation costs will total at least \$3,500- \$7,000 for a three-year period – paid at the start of the first year -- with an additional \$500 in annual maintenance costs in years two and three. These additional costs will create an unnecessary burden on community pharmacies that receive an already low margin on DMEPOS products and services. Pharmacies that discontinue DMEPOS services will by definition no longer sell the following products: diabetes test supplies, canes, walkers, wheelchairs, portable commodes, compression hose, mastectomy prosthetics, neck and body orthotics, wound care, and other vital products and services.

We are hearing from our members that these costs will drive them out of the program. A late March, 2009 national survey showed that of those independent community pharmacies currently providing Part B DMEPOS: 1) 31% will drop out of the program due to the new requirements; and 2) of those that have completed an accreditation application but have not been surveyed, 73% will need an extension to meet the accreditation deadline. The result of fewer independent pharmacies participating in the program will be that beneficiaries in underserved areas will be forced to travel dozens of additional miles for supplies and expert advice previously obtained closer to home. Ironically, the new CMS DMEPOS regulations will pressure Medicare patients towards mail order and internet operations, where fraud is believed to be most prevalent.^{6, 7, 8}

⁶ On the list of Excluded Individuals and Entities on the GAO website, under the broadest definition of fraud possible, at most 0.71% of all pharmacies can be said to have engaged in some kind of fraud – technical or otherwise. That statistic is overbroad, as it includes DME and other fraud, and it over counts pharmacies.

⁷ A recent NCPA/NACDS study conducted by Accenture, as well as the European Alliance for Access to Safe Medicines found that unregulated online drug operators have been found to cause harm and even death in some cases. Counterfeit drugs are driven almost entirely by unlicensed, rogue Internet Web sites. Some 68% of medications purchased online are fake or sub-standard and 95.6% of Internet pharmacy sites are operating illegally.” [1] European Alliance for Access to Safe Medicines, The Counterfeiting Superhighway, June 2008. The full report is available at www.eaasm.eu.

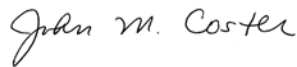
Finally, we highlight two key provisions that fail to protect small businesses, particularly pharmacies, from possible participation in the competitive bidding program:

- CMS' \$3.5 million small business definition (which CMS now uses even though it used a \$6 million figure in last year's final rule regarding accreditation and a \$6.5 million figure in the AMP final rule) further forces independent community pharmacists out of the program. In addition, the revenues of all the stores of an independent community pharmacy owner are combined to see if it exceeds the \$3.5 million small business ceiling.
- The 30% target number for small bidder participation does not adequately allow suppliers to band together to submit acceptable bids, as CMS had envisioned.

For all the reasons highlighted above, NCPA reiterates its requests that CMS: 1) exercise its existing authority to conditionally exempt pharmacies from the accreditation and surety bond requirements; 2) continue to exempt retail diabetes test supplies from all future round of competitive bidding; and 3) Issue a new competitive bidding rule through renewed rulemaking procedures that will implement the competitive bidding program in a manner that better ensures quality standards and ensures the ability of small businesses to participate in the program.

NCPA appreciates the opportunity to comment on CMS-1413-P. Please do not hesitate to contact Tony Lee, Esq., Director of Public Policy at tony.lee@ncpanet.org or John Coster at john.coster@ncpanet.org, (703) 683-8200) if you have any questions.

Sincerely,



John Coster
Ph.D., R. Ph.
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Encl: April, 2009 memorandum from Bryan Cave LLP

⁸ Further evidence of the magnitude of the problem was demonstrated in Congressional testimony by GoDaddy.com, a leading online registrant, which revealed it has had to suspend 6,000 of these rogue sites in the first half of 2008 as a result of their practices. Testimony of Christine N. Jones, General Counsel and Corporate Secretary, Go Daddy Group Inc., Before the House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security United States House of Representatives, June 24, 2008 hearing on Online Pharmacies And The Problem of Internet Drug Abuse.