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June 21, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
The Centers for Medicare and Medicaid Services  
P.O. Box 8011  
Baltimore, MD 21244-1850

**Subject File: CMS-1500-P**

Dear Dr. McClellan:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on that portion of the proposed rule published in the *Federal Register* on May 4, 2005, concerning proposed changes to the Hospital Inpatient Prospective Payment System (HIPPS) for fiscal year 2006. Specifically, ACCP is concerned that the proposed rule does not reinstate funding eligibility for 2<sup>nd</sup> year and specialized pharmacy residencies within the provisions for graduate medical education contained in 42 CFR Parts 412 and 413.

ACCP is a national professional and scientific society that represents almost 10,000 clinical pharmacist practitioners, researchers, and educators. Our members have been among the profession's leaders for almost three decades in providing professional services, consultation, cutting-edge clinical research, and educational leadership that improve the quality of medication use in the health care settings in which they practice.

More than 80 percent of ACCP's members have completed either a one-year pharmacy practice residency or a two (or greater)-year residency in a specialized area of pharmacy practice. Twenty-five percent of ACCP's members are board certified in one or more of the five pharmacy specialties recognized and certified by the Board of Pharmaceutical Specialties. Together with the American Society of Health-System Pharmacists (ASHP), which is the CMS-recognized accrediting body for hospital-based pharmacy residency training, ACCP has provided primary leadership within the pharmacy profession over the past quarter century in fostering the growth and development of residency training in pharmacy as an essential element of the educational preparation of pharmacists involved in the provision of contemporary pharmacy services.

Despite its initial proposal in 2003 to eliminate pass-through funding eligibility for all pharmacy residencies, CMS was ultimately persuaded by the comments from the pharmacy profession and others to amend its proposal and to continue funding eligibility for pharmacy practice (“first year”) residencies. Additionally, at that time, the agency indicated that it would entertain the possibility of restoring funding eligibility for 2<sup>nd</sup> year/specialized pharmacy residencies at the point in time when it could be demonstrated that such training represented the “industry norm” for pharmacists practicing in those specialized areas.

The recent provision by ASHP of national survey data collected in 2004, which found that 82 percent of hospitals that employ clinical pharmacy specialists require specialized pharmacy residency training for those practitioners, demonstrates clearly that such training does indeed represent the “industry norm” for contemporary hospital pharmacy practice. Among these hospitals, nearly one-fifth will not fill a specialized clinical pharmacy position with someone who has not completed such a residency; the remainder will do so only if a specialty-residency trained candidate is not available.

In its previous ruling, CMS defined “industry norm” as meaning “that more than 50 percent of hospitals in a random, statistically valid sample require the completion of a particular training program before an individual may be employed in a specialty.” ASHP submitted these survey results to CMS in July 2004 and again in March 2005.

Thus we believe that the standard that CMS imposed for restoring funding eligibility for 2<sup>nd</sup> year and specialized pharmacy residencies has now been clearly demonstrated to exist in the hospital practice setting. We would therefore strongly urge CMS to revise the proposed rule to reinstate Medicare pass-through funding eligibility for 2<sup>nd</sup> year and specialized pharmacy residencies beginning in fiscal year 2006.

As we noted in our letter of 2003, there are many substantive reasons that are far more important than the “industry norm” standard that CMS chose to impose in 2003 that should persuade CMS to allow, and even actively support, funding for both pharmacy practice and specialized pharmacy residencies. These include:

- The various recent reports from the **Institute of Medicine** outlining the critical importance of, among other things, (a) improved medication management for chronic diseases; (b) the necessity for enhanced interdisciplinary training and team-building in the delivery of high quality health care services; and (c) the critical need for closing the “quality chasm” in health care by improving the safety of, among many other elements, medication use. These are precisely the types of activities that pharmacy residency training prepares the contemporary pharmacist to perform. **In particular, it is during the residency training experience (for both disciplines) that essential and valuable professional relationships and trust are established between physicians and pharmacists that lead to more collaborative and effective management of patients’ drug therapy.**

- The recommendation of the **Medicare Payment Advisory Commission** to Congress in June 2002 that the Secretary of HHS "...assess models for collaborative drug therapy management services" by clinical pharmacists working with physicians. Pharmacy residency training is an integral and essential component of the training of pharmacists to perform collaborative drug therapy management.
- **Congressional concern about the nation's shortage of pharmacists AND the pharmacy faculty needed to educate them has resulted in the introduction of the Pharmacy Education Aid Act in both the 107<sup>th</sup> and 108<sup>th</sup> Congress.** It is well recognized that the nation's need for qualified pharmacy faculty has never been greater as pharmacy schools seek to expand to meet the unprecedented demand for pharmacists detailed in the December 2000 report of the Bureau of Health Professions. For more than two decades, completion of residency training has been an essential criterion for employment of their clinical faculty by schools and colleges of pharmacy. Reduced support for residency training in pharmacy will only compound this faculty shortage.
- Completion of a pharmacy residency is among the key qualifying criteria for persons seeking to become certified by the **Board of Pharmaceutical Specialties** as a pharmacotherapy specialist. The growing cadre of pharmacotherapists in the U.S. will inevitably be at the forefront in assuring that drug therapy is effective, safe, and well-managed within our health care system.
- **The implementation and future success of the Medicare Part D prescription drug benefit in 2006 and beyond.** Pharmacy residency programs provide the essential experiences, skills development, and knowledge needed to manage and deliver the highest quality medication therapy management programs.

ACCP also noted in its 2003 comments that the likely rationale for eliminating funding eligibility for pharmacy residencies was to help control costs to Medicare associated with payments for graduate medical, nursing, and allied health professions education. Our estimates at that time suggested that total Medicare funding for pharmacy residency training in the U.S. was likely to be less than 0.1% of total GME funding. This amount (certainly less than \$10 million/year) is practically inconsequential in the larger scheme of Medicare, and yet its loss for pharmacy is disproportionately devastating to the profession and to residency programs that provide the leadership to improve the quality of medication use in hospitals and health systems. Since funding eligibility for pharmacy practice residencies (which constitute the majority of pharmacy residency training in hospitals) was ultimately retained, the negative financial impact on Medicare of supporting 2<sup>nd</sup> year and specialized pharmacy residencies would now be, by any reasonable measure, truly microscopic within the total Medicare budget.

Mark B. McClellan, M.D., Ph.D.

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In summary, ACCP believes that the proposed rule concerning HIPPS payment rules for fiscal year 2006 related to GME funding should be revised to reinstate funding eligibility for 2<sup>nd</sup> year and specialized pharmacy residency training programs. We urge CMS to recognize the enormously positive benefit-to-cost ratio of this reinstatement, and look forward to a favorable decision in this regard.

Please do not hesitate to follow up with us if we can provide additional information or assistance on this important matter.

Sincerely,



Michael S. Maddux, Pharm.D., FCCP  
Executive Director

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Director, Government & Professional Affairs

cc: ACCP Board of Regents