Recommendations: *AMA Scope of Practice Data Series: Pharmacists*

Submitted by the Accreditation Council for Pharmacy Education, American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, National Association of Boards of Pharmacy, and National Alliance of State Pharmacy Associations

Section II: Introduction

General comments:

- Codification via state statutes and regulations of the practice of collaborative drug therapy management (CDTM), as well as other domains of the practice of pharmacy, is the appropriate, legitimate process to accurately define and regulate the domains and scope of practice of pharmacists. The statutes and regulations related to direct patient care are consistent with the current education, training, regulation, and certification of pharmacists in the provision of contemporary medication-related health care services. This codification process is open to public and professional scrutiny, discussion, and debate and, as reflected in its adoption in all but four states, is now a standard of care.

- We have concerns that the CDTM language in this section inaccurately equates (and therefore confuses) the practice of CDTM, an inherently interprofessional and interdependent practice activity with "efforts" to expand the scope of practice of pharmacists into areas that are suggested to be exclusive to the practice of medicine. While we accept the view that the practice of medicine is quite expansive, with a wide range of patient care activities and domains serving as its framework, that does not mean that the performance of any one of those myriad functions or patient care activities by another health professional who is appropriately educated and licensed to perform that function, somehow constitutes the "practice of medicine."

Comments on specific parts of this section:

- Page 5, first column, second paragraph: Pharmacists have been recognized as medication management providers since the 1970s, when the conditions for nursing homes' participation in Medicare and Medicaid were strengthened to include a drug regimen review to be performed at least monthly by a licensed pharmacist. These standards included requirements for control, accountability, and proper labeling of medications and biologicals, as well as the establishment of a pharmaceutical services committee, which required the formal participation of a pharmacist.

  This mandate was "based on the assumption that as a discipline specializing in the proper use of medication, pharmacists would be able to solve drug therapy problems that others could not," according to a 1997 article in the *Journal of Managed Care Pharmacy*. This

important milestone in pharmacy history and in the evolution of pharmacy practice is a notable omission from the Introduction section of the document.

- Page 5, first column, third paragraph: To provide an accurate perspective for the reader, pharmacists' current scope of practice outside of CDTM should be presented in the document. It is within the scope of practice in all 50 states for pharmacists in all practice settings to obtain medication histories, review the patient's medications to identify medication-related problems, intervene with the physician to resolve identified problems, educate the patient about proper use of medications, encourage adherence with prescribed medications, and document and communicate information to the physician. These medication therapy management (MTM) activities are part of a pharmacist's responsibility to ensure optimal therapeutic outcomes for the patients they serve. The Asheville Project services and the Medicare Modernization Act's authorized MTM services referenced in the Introduction fall within the pharmacist's normal scope of practice and do not require CDTM agreements, although a collaborative relationship between the pharmacist and physician are strongly encouraged. CDTM provides an expanded role for the pharmacist that often involves modifying or initiating medication therapy and ordering laboratory tests while working under a collaborative practice agreement (CPA) with a physician. A copy of *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians,* developed by the Council on Credentialing in Pharmacy (CCP), is provided with these recommendations for your reference.

- Page 6, column 1, first paragraph: As successful CDTM models in all pharmacy practice settings continue to emerge, so does the scientific literature to support the pharmacist's role in these collaborative care models. We recommend that this section be updated with more current scientific studies than those cited. To promote a team-based approach to care, the section should highlight current successful CDTM models in the community pharmacy setting that use health information technology and proactive physician–pharmacist working relationships for the delivery of quality patient care. The inclusion of pharmacists and medication therapy management services in the recently enacted health care reform legislation is further evidence that pharmacists have an important role to play on the health care team in coordinated care models.

- Page 6, column 1, second paragraph: This paragraph and others in the document need to be edited to recognize that standards have been in place for the training of doctor of pharmacy (PharmD) candidates since 1997, with the most recent version adopted in 2006 and implemented in 2007 (www.acpe-accredit.org/pdf/ACPE_Revised_PharmD_Standards_Adopted_Jan152006.pdf). The Accreditation Council for Pharmacy Education (ACPE) is the body that accredits

colleges or schools of pharmacy providing PharmD training and maintains rigorous requirements for didactic and experiential training of pharmacists. In addition, the standards require that students develop competence in collecting and assessing subjective and objective clinical information as a means to monitor therapeutic progress in all practice settings. This includes methods for collecting information from the patient and the physician if the pharmacist and physician are not working in the same location (e.g., community pharmacy setting).

- Page 6, column 1, third paragraph: We recommend correcting several statements in this paragraph. "*Neither the practice experiences nor the didactic component of the pharmacist education prepares a pharmacy student to develop the clinical judgment similar to a physician …"* The goal of ACPE's Standards 2007 is not to train physician equivalents, but rather to educate and train pharmacists with the knowledge, skills and behaviors necessary to provide medication therapy management (MTM), especially related to chronic disease monitoring and management. The current education of pharmacy graduates does provide for the clinical judgment required for the patient care activities to be undertaken by pharmacists in practice, as evidenced by student assessment data collected by pharmacy colleges and schools.

  Continuing with the statement above, "… *with regard to the diagnosis, assessment of illness/condition, formulation of a treatment plan, or the provision of independent medical care or medication therapy*." We call AMA's attention to the 2007 ACPE standards. The standards do provide for competencies noted here appropriate to the context of collaborative MTM involving pharmacists. Of note, involvement of pharmacists in interprofessional-provided patient care, a hallmark of Institute of Medicine (IOM) recommendations for improving the U.S. health care system, rather than "independent medical care" is stressed throughout Standards 2007 (see Standards 1, 6, 9, 12, and 28).

  The statement, "*To protect patients' health and safety, physicians considering entering into CPAs with pharmacists should assess whether the education, training, and expertise of a pharmacist adequately equips him or her to initiate, monitor, and/or modify therapeutic regimens prescribed by physicians*," and other statements in the AMA document imply or suggest that MTM activities by pharmacists are detrimental to patient health and unsafe. No evidence is provided to substantiate these claims. The majority of evidence in the literature regarding pharmacist participation in collaborative MTM suggests the exact opposite of the unfounded assertions of the AMA. On face value, the second part of this statement is appropriate guidance. However, in the context of suggested inferior and unsafe education and training, it is offered as a "warning" which could dissuade physicians from entering CPAs and MTM agreements that would benefit

their patients and bring new patients into their practices. If this is the intent of the AMA, then this direction is quite counter to IOM recommendations and a continuation of turf battles that mar the ultimate effectiveness of the U.S. health care system.

- Page 6, second column, first paragraph: According to the recently released 2009 Pharmacists Workforce Survey[1], the proportion of licensed pharmacists with a PharmD has increased to 21.6% from 18.6% in 2005.

- Page 6, second column, second paragraph: The statement, "*To provide comprehensive CDTM, the pharmacist must secure the consent of all the physicians who prescribe medications for the patient*," implies an onerous, unwieldy model of care which has the potential to negatively affect patient outcomes. Pharmacists providing medication therapy management take into account all of the patient's medications and communicate with relevant providers about specific medications they have prescribed. The activities a pharmacist can perform under a collaborative practice agreement (CPA) are specifically outlined in the agreement, in accordance with established evidence-based clinical guidelines, and if a medication is not covered under the agreement, then the pharmacist would have an obligation to contact the appropriate physician.

- Page 7, first column, top of the page: The concerns raised about privacy issues with regard to obtaining histories and sensitive medical information in public/community retail settings should be clarified. Community pharmacies are bound by the same HIPAA requirements as physicians, and pharmacies have semiprivate or private areas where these activities occur. In addition, pharmacists are trained just as physicians are to respect and maintain patient confidentiality and privacy.

Section III: Pharmacy as a Profession

Definition(s)

- Page 8, footnotes: References 2 and 3 on this page are transposed. The Bureau of Labor Statistics (BLS) reference should be reference 2 instead of 3 and should be updated to reflect the 2010–11 BLS edition (same website). The AACP reference should be 3 instead of 2 and the website should be www.aacp.org, not www.apa.org.

[1] Web. American Association of Colleges of Pharmacy (AACP). http://www.aacp.org/resources/research/pharmacymanpower/Documents/2009%20National%20Pharmacist%20Workforce%20Survey%20-%20FINAL%20REPORT.pdf. Retrieved April 15, 2009.

Specialization

- Page 8, column 2, first paragraph: The first sentence in this section should be clarified to indicate that specialties and certification of specialists, under the structure of the Board of Pharmacy Specialties (BPS), are recognized by the majority of national pharmacist organizations. Also, the name of BPS has changed and should be listed as "the Board of Pharmacy Specialties." It should also be noted that a sixth new specialty in ambulatory care is under development and will be initiated in 2011.

- Page 8, column 2: A section should be added to recognize that the Commission for Certification in Geriatric Pharmacy (CCGP) provides board certification in geriatric pharmacy. The following is suggested text:

  Geriatric pharmacy (recognized by CCGP as of 1997): the pharmaceutical care of elderly patients. Certified Geriatric Pharmacists (CGPs) have demonstrated knowledge and skills in geriatric pharmacotherapy principles and advise seniors, caregivers, and health professionals on the appropriate use of medications in seniors. CGPs work in a variety of settings, including long-term care facilities, community-based offices and clinics, community pharmacies, academia, and managed care/pharmacy benefit management companies.

Brief history of the profession

- As mentioned previously, the 1970s brought about groundbreaking federal regulatory requirements for the clinical services of a pharmacist to review every resident's medication regimen at least monthly in nursing facilities and at least quarterly in intermediate care facilities for the mentally retarded (ICF-MRs). Additionally, in recent decades (1990s to present day), many states require the clinical services of a pharmacist in the assisted living setting to review residents' medication regimens. This information should be added to this section of the document.

Demographics

- Page 10, column 2, first paragraph: Recommend updating the Bureau of Labor Statistics data for 2010–11. In 2008, pharmacists held approximately 269,900 jobs. According to the National Association of Boards of Pharmacy, there were 401,969 pharmacist licenses in the United States, including Guam and Puerto Rico, in 2009. Of these, there were 264,527 pharmacist licenses with in-state addresses.[2]

[2] National Association of Boards of Pharmacy Survey of Pharmacy Law - 2010. National Association of Boards of Pharmacy. 2009. Available from www.nabp.net.

- Page 11, column 1, first paragraph: As stated previously, the 2009 Pharmacist Workforce Survey found that he proportion of licensed pharmacists who held a PharmD as their highest degree increased from 13.9% in 2000 to 18.6% in 2005 and 21.6% in 2009.

Asheville Project

- Page 11, second column, second paragraph: The first line should read "APhA," not "AphA."

- Page 13, second column, third paragraph: Consider expanding the end of this section to include information on the APhA Foundation's Diabetes Ten City Challenge (DTCC), which was implemented in 10 cities nationwide and demonstrated results similar to the Asheville Project (include reference). Additionally, increases in preventative care measures were demonstrated, including the number of people with current influenza vaccinations, eye exams, and foot exams.[3]

Section IV: Billing for Services

General comments

- This section contains no information on the approval by the American Medical Association's CPT Editorial Panel in 2007 of three specific, Category I CPT codes for the documentation of and billing for pharmacists' face-to-face patient care/medication therapy management services. These codes, which transitioned from Category III codes approved less than 2 years earlier, are now accepted and utilized by a wide range of both private and public payers, consistent with the industry standard for use of CPT codes by most health professionals in coding and billing for professional services.

- We recommend an acknowledgement that the Centers for Medicare and Medicaid Services (CMS) requires that billing for pharmacists' direct patient care services must be accomplished using the ANSI ASC X12-837 electronic transaction for services of health professionals.

- We recommend including in this section that the 2000 CMS final rule codified the inclusion of pharmacists among health professionals eligible to obtain and utilize National Practitioner Identifier (NPI) numbers.

[3] Diabetes Ten City Challenge: Final economic and clinical Results. *J Am Pharm Assoc.* 2009;49e52-e60

Definition of MTM

- Page 14, column 2, first paragraph: We recommend updating this section to include the 2010 CMS guidelines that provide a more standardized approach for Part D MTM service delivery.
    - All eligible patients must receive a comprehensive medication review and quarterly targeted follow-up medication reviews.
    - The services must be delivered in a person-to-person format (face-to-face or telephonically).
    - The criteria for targeting patients have been standardized. We recommend clarifying this information in the document on page 16.

- Page 14, column 2, second paragraph: We are pleased that the pharmacy profession's MTM definition is included in the document. We recommend clarifying that the definition is not limited to Medicare.
- Page 15, first column, second paragraph: Please correct "National Association of Chain Drug Stores" to "National Association of Chain Drug Stores Foundation."

Characteristics of plans providing MTM services

- Page 16, column 1, first paragraph: We recommend clarifying the statement "*MTM is available to beneficiaries through Medicare Part D for an additional cost*." Currently, patients do not pay for these services, not even co-pays. Rather, they are provided as part of the plan's administrative costs as a quality improvement benefit.

- Page 16, column 1, second paragraph: Consider updating this section with the new CMS requirements for 2010. Plans *cannot* require more than eight chronic Part D drugs as the minimum number of drugs and more than three chronic diseases as the minimum number of multiple chronic diseases. In addition, sponsors must target at least four of the following seven core chronic conditions:
    - Hypertension
    - Heart failure
    - Diabetes
    - Dyslipidemia
    - Respiratory disease, such as asthma, chronic obstructive pulmonary disease (COPD) or chronic lung disorders
    - Bone disease/arthritis, such as osteoporosis, osteoarthritis, or rheumatoid arthritis
    - Mental health, such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders

Section V: Education of Pharmacists

Doctor of Pharmacy Degree

- Page 17, second column, first paragraph: The information presented regarding the prepharmacy educational requirements needs to be updated in this paragraph and several other places in this section. Historically, the doctor of pharmacy preprofessional requirements were a minimum of 2 years of college education, heavily emphasizing math and science education. Several schools have now introduced a 3-year prepharmacy requirement, and some require a baccalaureate degree. As published in the March 2010 issue of *Academic Medicine* (page 566), 65% of students matriculated into the professional degree program having completed 3 or more years of college education, and 43% of these students hold a baccalaureate or higher degree.[4]

Number of U.S. Schools

- Page 18, second column: Current ACPE statistics report the following number of pharmacy programs:
    - 120 colleges and schools with accreditation status
        - 94 colleges and schools with full accreditation status
        - 18 colleges and schools with candidate status
        - 8 colleges and schools with precandidate status

Accrediting organization

- Page 18: We recommend including a reference or link as previously provided to the current ACPE Standards 2007 in this section.

Pharmacy College Admissions Test entrance examination

- Page 20, column 2, paragraph 1: PCAT currently is a product of Pearson, not Harcourt Assessment.
- Page 21, column 1, first sentence: We recommend adding a statement regarding the studies demonstrating the predictive correlation between PCAT and performance, such that performance on PCAT is highly predictive of first-year academic performance in the PharmD curriculum.[5]

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[4] Jennifer M. Patton; Lucinda L. Maine, RPh, PhD, Rebecca M. Morgan, MPA, AM Last Page: The Doctor of Pharmacy (PharmD) Degree, Academic Medicine. 85(3):566, March 2010.

[5] Nathan R. Kuncel, PhD, Marcus Credé, MA, Lisa L. Thomas, BS, David M. Klieger, JD, Stephanie N. Seiler, BS, and Sang E. Woo, BS. A Meta-Analysis of the Validity of the Pharmacy College Admission Test (PCAT) and Grade Predictors of Pharmacy Student Performance, *Amer J of Pharm Educ.* 69:article 51, 2005.

Pharmacy school curriculum

- Page 21, "*Survey of didactic component*": The information for the "Survey of the didactic component" was based on a survey of three schools (reference 87) and was retrieved from Web sites on October 15–22, 2006. ACPE Standards 2007, although released in 2006, did not become effective until July 1, 2007. Under present procedures, ACPE has asked all colleges and schools of pharmacy to map their curriculum both to the competency expectations of the standards (Standard 12) and the curricular content areas provided in Appendix B of the standards. Moreover, Standard 15 requires assessment and evaluation of student learning and curricular effectiveness, including achievement of the Standard 12 competencies. Of note, the curricular information provided in the AMA document does not reflect current curricular activities being undertaken by accredited pharmacy programs. This is important because the competency/assessment expectations and the curricular content information in Appendix B contains expectations in support of the pharmacy graduate's ability to provide MTM, as does the guidance provided for the experiential component of the standards under Standard 14 and Appendix C. We recommend that AMA incorporate the curricular content areas from Appendix B of the standards instead of the survey of three schools in order to provide an accurate representation of pharmacy school curricula, as three schools out of more than a hundred is not an appropriate sample.

Practice experience component

- Page 23, second column, last sentence: The statement "*Neither the ACPE nor state licensing requirements mandate direct patient contact as requirement for student practice experience*" is erroneous, flawed and disturbing. As illustrated in ACPE's Standards 2007, significant direct patient contact is required and necessary for students to develop the clinical skills needed to provide effective care. The following is extracted from Guideline 14.5 of Standards 2007:

  The organization of the advanced pharmacy practice experiences should provide a balanced series of required (the majority) and elective experiences that cumulatively provide sustained experiences of adequate intensity, duration, and breadth (in terms of patients and disease states that pharmacists are likely to encounter when providing care) to enable achievement of stated competencies as demonstrated by assessment of outcome expectations. Generally, the required and elective experiences should be full-time, provide continuity of care, and be conducted under pharmacist-preceptor supervision and monitoring.
  The required advanced pharmacy practice experiences should emphasize the need for continuity of care throughout the health care delivery system, including the availability and sharing of information regarding a patient's condition, medications, and other therapies.

Postgraduate training for pharmacists

- Page 24, column 2: The acronyms used to for residency training need to be corrected throughout this section. Postgraduate year one residencies are denoted as "PGY1" residencies, and the acronym "PGY2" should be used for postgraduate year 2 residencies.
- Page 24, column 2, second paragraph: It should be clarified that the American Society of Health-System Pharmacists, in collaboration with APhA, has promulgated PGY1 community pharmacy residency standards.

Section VI: Collaborative Drug Therapy Management

Introduction

- Page 26, first column, second paragraph: We recognize the variability in both reporting and classification of CDTM at the state level and would welcome the opportunity to work directly with AMA and other interested parties to seek better organization, clarity, and consistency of these data to enhance their utility by the health care community.

Collaborative practice agreement

- Page 27, column 2, second paragraph: In the first sentence, the term "collaborative protocol agreement" appears; this document should be described consistently throughout the document as a "collaborative practice agreement."
- Page 27, second column, second paragraph: In the sentence "*It is imperative that a physician entering into a CPA with a pharmacist be cognizant of the limited training a pharmacist* …," we suggest that the term "limited" used to describe the training of pharmacists in comparison to physicians should be replaced by the term "differentiated," unless the specifics of those "limits" (e.g., time in training, curriculum, etc.) are explicitly delineated and substantiated.

CDTM services

- Page 28, first column, third paragraph: The tone of the first sentence in this paragraph is concerning, and we recommend editing it to focus on the positive aspects of pharmacist involvement in laboratory testing. Pharmacists in most states provide Clinical Laboratory Improvement Amendments–waived laboratory tests. These tests provide useful information in monitoring medications, and as electronic health records are implemented, laboratory data generated through these tests can be added to the patient's medical record.

Section VII: State Licensure and Regulations

National specialty certification

- Page 30: Please change the name of BPS to the Board of Pharmacy Specialties. Consider adding the BPS website (www.bpsweb.org) to the document so the most up-to-date information can be obtained.
- We recommend mentioning in this section that an ambulatory care specialty is under development with anticipated release in 2011.
- We also recommend noting the availability of recognition by portfolio review of added qualifications in the areas of cardiology and infectious diseases within the specialty of pharmacotherapy.
- Page 30: As referenced on page 4 of this appendix, a section should be added to recognize that the Commission for Certification in Geriatric Pharmacy (CCGP) provides board certification in geriatric pharmacy.

Section VIII: Professional Organizations

The following professional organizations require updating in Section VIII:

- Page 31: American Pharmacists Association
  Please update the address to
  2215 Constitution Avenue NW
  Washington, DC 20037
  Please update the website towww.pharmacist.com.

- Page 32: American College of Clinical Pharmacy
  The "tag line" and website for the American College of Clinical Pharmacy remain accurate. The correct addresses are the following:
  ACCP National Headquarters
  13000 W. 87th Street Parkway
  Suite 100
  Lenexa, KS 66215
  913-492-3311
  ACCP Washington Office
  1455 Pennsylvania Avenue NW
  Suite 400
  Washington, DC 2004-1017
  202-621-1820

- Page 32: Please add the following to the list of organizations:

American Association of Colleges of Pharmacy (AACP)
Founded in 1900, the American Association of Colleges of Pharmacy (AACP) is a national organization representing the interests of pharmacy education and educators. Comprising 116 accredited colleges and schools of pharmacy including more than 5,500 faculty, 52,000 students enrolled in professional programs and 5,400 individuals pursuing graduate study, AACP is committed to excellence in pharmacy education.

1727 King Street, Floor 2
Alexandria, VA 22314
Phone: 703-739-2330
www.aacp.org

Section IX: Professional Journals of Interest

The following professional journals need to be included in Section IX:

- ***The American Journal of Pharmaceutical Education* (*www.ajpe.org*)**
- ***Pharmacotherapy (www.pharmacotherapy.org*)**
- ***The Consultant Pharmacist (www.ascp.com/publications/tcp/)***